

Generic Name:
Lepirudin

Designated Indication:
Treatment of heparin-associated thrombocytopenia type II.

Trade Name (if present):
Refluden

Date Designated 2/13/1997
Date Approved 3/6/1998

Sponsor Contact Information
Hoechst Marion Roussel
Frankfurt am Main
P O. Box 1140
Marburg
GERMANY

Generic Name:
Rifapentine

Designated Indication:
Treatment of pulmonary tuberculosis.

Trade Name (if present):
Priftin

Date Designated 6/9/1995
Date Approved 6/22/1998

Sponsor Contact Information
Hoechst Marion Roussel
P.O. Box 9627
Mail Station. H3-M2516
Kansas City MO 64134-0627

Generic Name:
Eflornithine HCl

Designated Indication:
Treatment of Trypanosoma brucei gambiense infection (sleeping sickness)

Trade Name (if present):
Ornudyl

Date Designated 4/23/1986
Date Approved 11/28/1990

Sponsor Contact Information
Hoechst Marion Roussel
P.O. Box 9627
Kansas City MO 64134

Generic Name:
Rifampin

Designated Indication:
For antituberculosis treatment where use of the oral form of the drug is not feasible

Trade Name (if present):
Rifadin I.V.

Date Designated 12/9/1985
Date Approved 5/25/1989

Sponsor Contact Information
Hoechst Marion Roussel
P.O. Box 9627
Kansas City MO 64134

Generic Name:
Rifampin, isoniazid, pyrazinamide

Designated Indication:
For the short-course treatment of tuberculosis.

Trade Name (if present):
Rifater

Date Designated 9/12/1985
Date Approved 5/31/1994

Sponsor Contact Information
Hoechst Marion Roussel
P.O. Box 9627
Kansas City MO 64134

Generic Name:
Rifapentine

Designated Indication:
Treatment of Mycobacterium avium complex in patients with AIDS

Trade Name (if present):
Priftin

Sponsor Contact Information
Hoechst Marion Roussel , Inc
P O. Box 9627
Mail Station H3-M2516
Kansas City MO 64134-0627

Date Designated 6/9/1995
Date Approved

Generic Name:
Rifapentine

Designated Indication:
Prophylactic treatment of Mycobacterium avium complex in patients with AIDS
and a CD4+ count less than or equal to 75/mm3.

Trade Name (if present):
Priftin

Sponsor Contact Information
Hoechst Marion Roussel, Inc
P O Box 9627
Mail Station: H3-M2516
Kansas City MO 64134-0627

Date Designated 3/12/1996
Date Approved

Generic Name:
Peginterferon alfa-2a

Designated Indication:
Treatment of chronic myelogenous leukemia.

Trade Name (if present):
PEGASYS

Sponsor Contact Information
Hoffman-La Roche Inc.
340 Kingsland St
Nutley NJ 07110-1199

Date Designated 9/30/1999
Date Approved

Generic Name:
Peginterferon alfa-2a

Designated Indication:
Treatment of renal cell carcinoma

Trade Name (if present):
PEGASYS

Sponsor Contact Information
Hoffman-La Roche Inc.
340 Kingsland St
Nutley NJ 07110-1199

Date Designated 7/13/1998
Date Approved

Generic Name:
Clonazepam

Designated Indication:
Treatment of hyperekplexia (startle disease)

Trade Name (if present):
Klonopin

Sponsor Contact Information
Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110

Date Designated 8/4/1994
Date Approved

Generic Name:
Daclizumab

Designated Indication:
Prevention of acute renal allograft rejection

Trade Name (if present):
Zenapax

Date Designated 3/5/1993
Date Approved 12/10/1997

Sponsor Contact Information
Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Humanized anti-tac

Designated Indication:
Prevention of acute graft-vs-host disease following bone marrow transplantation.

Trade Name (if present):
Zenapax

Date Designated 3/5/1993
Date Approved

Sponsor Contact Information
Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110-1199

Generic Name:
Tretinoin

Designated Indication:
Treatment of acute promyelocytic leukemia.

Trade Name (if present):
Vesanoid

Date Designated 10/24/1990
Date Approved 11/22/1995

Sponsor Contact Information
Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Interferon alfa-2a (recombinant)

Designated Indication:
For the concomitant administration with Teceleukin for the treatment of metastatic renal cell carcinoma

Trade Name (if present):
Roferon-A

Date Designated 5/2/1990
Date Approved

Sponsor Contact Information
Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Interferon alfa-2a (recombinant)

Designated Indication:
For the treatment of metastatic malignant melanoma in combination with Teceleukin

Trade Name (if present):
Roferon-A

Date Designated 5/11/1990
Date Approved

Sponsor Contact Information
Hoffmann-La Roche, Inc.
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Interleukin-2

Designated Indication:

In combination with interferon alfa-2a for the treatment of metastatic malignant melanoma

Trade Name (if present):
Tecelukin

Date Designated 5/11/1990
Date Approved

Sponsor Contact Information

Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Interleukin-2

Designated Indication:

In combination with interferon alfa-2a for the treatment of metastatic renal cell carcinoma

Trade Name (if present):
Tecelukin

Date Designated 5/3/1990
Date Approved

Sponsor Contact Information

Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Fluorouracil

Designated Indication:

For use in combination with interferon alpha-2a, recombinant, for the treatment of advanced colorectal carcinoma.

Trade Name (if present):

Date Designated 4/18/1990
Date Approved

Sponsor Contact Information

Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110-1199

Generic Name:
Interferon alfa-2a (recombinant)

Designated Indication:

For the concomitant administration with fluorouracil for the treatment of advanced colorectal cancer.

Trade Name (if present):
Roferon-A

Date Designated 5/14/1990
Date Approved

Sponsor Contact Information

Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110-1199

Generic Name:
Fluorouracil

Designated Indication:

For use in combination with interferon alpha-2a, recombinant, for the treatment of esophageal carcinoma

Trade Name (if present):

Date Designated 10/27/1989
Date Approved

Sponsor Contact Information

Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110-1199

Generic Name:
Interferon alfa-2a (recombinant)

Designated Indication:
For use in combination with fluorouracil for the treatment of esophageal carcinoma.

Trade Name (if present):
Roferon-A

Date Designated 10/27/1989
Date Approved

Sponsor Contact Information
Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110-1199

Generic Name:
Interferon alfa-2a

Designated Indication:
Treatment of chronic myelogenous leukemia

Trade Name (if present):
Roferon A

Date Designated 6/6/1989
Date Approved 10/19/1995

Sponsor Contact Information
Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Interleukin-2

Designated Indication:
Treatment of metastatic renal cell carcinoma

Trade Name (if present):
Teceleukin

Date Designated 2/5/1990
Date Approved

Sponsor Contact Information
Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Interleukin-2

Designated Indication:
Treatment of metastatic malignant melanoma

Trade Name (if present):
Teleleukin

Date Designated 2/6/1990
Date Approved

Sponsor Contact Information
Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Zalcitabine

Designated Indication:
Treatment of AIDS.

Trade Name (if present):
Hivid

Date Designated 6/28/1988
Date Approved 6/19/1992

Sponsor Contact Information
Hoffmann-La Roche, Inc
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Interferon alfa-2a (recombinant)

Designated Indication:
Treatment of renal cell carcinoma.

Trade Name (if present):
Roferon-A

Date Designated 4/18/1988
Date Approved

Sponsor Contact Information
Hoffmann-La Roche, Inc.
340 Kingsland Street
Nutley NJ 07110-1199

Generic Name:
Interferon alfa-2a (recombinant)

Designated Indication:
Treatment of AIDS related Kaposi's sarcoma

Trade Name (if present):
Roferon-A

Date Designated 12/14/1987
Date Approved 11/21/1988

Sponsor Contact Information
Hoffmann-La Roche, Inc.
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Mefloquine HCl

Designated Indication:
Treatment of acute malaria due to Plasmodium falciparum and Plasmodium vivax.

Trade Name (if present):
Lariam

Date Designated 4/13/1988
Date Approved 5/2/1989

Sponsor Contact Information
Hoffmann-La Roche, Inc.
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Mefloquine HCl

Designated Indication:
Prophylaxis of Plasmodium falciparum malaria which is resistant to other available drugs

Trade Name (if present):
Lariam

Date Designated 4/13/1988
Date Approved 5/2/1989

Sponsor Contact Information
Hoffmann-La Roche, Inc.
340 Kingsland Street
Nutley NJ 07110

Generic Name:
Fluoxetine

Designated Indication:
Treatment of autism

Trade Name (if present):
Prozac

Date Designated 4/30/1999
Date Approved

Sponsor Contact Information
Hollander, MD, Eric
Mt. Sinai School of Medicine, Dept. of Psychiatry
Box 1230, One Gustave L. Levy Place
New York NY 10029-6574

Generic Name:
Dextran 70

Designated Indication:
Treatment of recurrent corneal erosion unresponsive to conventional therapy.

Trade Name (if present):
Dehydrex

Sponsor Contact Information
Holles Laboratories, Inc
30 Forest Notch
Cohasset MA 02025

Date Designated 3/5/1990
Date Approved

Generic Name:
Benzylpenicillin, benzylpenicilloic,
benzylpenilloic acid

Designated Indication:
Assessing the risk of administrating penicillin when it is the preferred drug of choice in adult patients who have previously received penicillin and have a history of clinical sensitivity.

Trade Name (if present):
Pre-Pen/MDM

Sponsor Contact Information
Hollister-Stier Laboratories LLC
PO Box 3145
Spokane WA 99220-3145

Date Designated 9/29/1987
Date Approved

Generic Name:
B Lymphocyte Stimulator

Designated Indication:
Treatment of common variable immunodeficiency (CVID)

Trade Name (if present):
BLyS

Sponsor Contact Information
Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville MD 20850

Date Designated 2/21/2001
Date Approved

Generic Name:
PA mAb

Designated Indication:
Treatment of anthrax

Trade Name (if present):
Abthrax

Sponsor Contact Information
Human Genome Sciences, Inc
9410 Key West Avenue
Rockville MD 20850

Date Designated 11/12/2003
Date Approved

Generic Name:
Clostridial collagenase

Designated Indication:
Treatment of advanced (involutional or residual stage) Dupuytren's disease.

Trade Name (if present):

Sponsor Contact Information
Hurst, L. M.D & Badalamente, M. Ph.D.
State University of New York at Stony Brook
School of Medicine, Health Sciences Center T18-020
Stony Brook NY 11794-8181

Date Designated 5/23/1996
Date Approved

Generic Name:
Iodine I 131 bis(indium-diethylenetriaminepentaacetic acid)tyrosyllysine/hMN-14 x m734 F(ab')2 bispecific monoclonal antibody

Designated Indication:
Treatment of small-cell lung cancer

Trade Name (if present):
Pentacea

Date Designated 2/22/2000
Date Approved

Sponsor Contact Information
IBC Pharmaceuticals, L.L.C.
300 American Rd
Morris Plains NJ 07950

Generic Name:
Phenylalanine ammonia-lyase

Designated Indication:
Treatment of hyperphenylalaninemia

Trade Name (if present):
Phenylase

Date Designated 3/8/1995
Date Approved

Sponsor Contact Information
Ibex Technologies, Inc.
5485 Pare
Montreal, Quebec

Generic Name:
Bis(4-fluorophenyl)phenylacetamide

Designated Indication:
Treatment of sickle cell disease.

Trade Name (if present):

Date Designated 3/2/2000
Date Approved

Sponsor Contact Information
ICAgan Inc.
Ion Channel Advances
PO Box 14487
Durham NC 27709

Generic Name:
toralizumab

Designated Indication:
Treatment of immune thrombocytopenic purpura

Trade Name (if present):

Date Designated 3/14/2002
Date Approved

Sponsor Contact Information
IDEC Pharmaceuticals Corporation
3030 Callan Road
San Diego CA 92121

Generic Name:
Humanized MAbs (IDECK-131) to CD40L

Designated Indication:
Treatment of systemic lupus erythematosus.

Trade Name (if present):

Date Designated 2/9/1999
Date Approved

Sponsor Contact Information
Idec Pharmaceuticals Corporation
3030 Callan Rd.
San Diego CA 92121

Generic Name:
IDN 6556

Designated Indication:
Treatment of patients undergoing solid organ transplantation

Trade Name (if present):

Date Designated 8/19/2003
Date Approved

Sponsor Contact Information
Idun Pharmaceuticals, Inc.

9380 Judicial drive
San Diego CA 92121

Generic Name:
Mitoguazone

Designated Indication:
Treatment of diffuse non-Hodgkin's lymphoma, including AIDS-related diffuse non-Hodgkin's lymphoma

Trade Name (if present):
apep

Date Designated 3/18/1994
Date Approved

Sponsor Contact Information
ILEX Oncology, Inc.
4545 Horizon Hill Blvd
San Antonio TX 78229-2263

Generic Name:
5,6-dihydro-5-azacytidine

Designated Indication:
Treatment of malignant mesothelioma.

Trade Name (if present):

Date Designated 5/11/1992
Date Approved

Sponsor Contact Information
ILEX Oncology, Inc.
4545 Horizon Hill Blvd
San Antonio TX 78229-2263

Generic Name:
clofarabine

Designated Indication:
Treatment of acute myelogenous leukemia

Trade Name (if present):
Clofarex

Date Designated 3/14/2002
Date Approved

Sponsor Contact Information
Ilex Products, Inc.
4545 Horizon Hill Blvd.
San Antonio TX 78229-2263

Generic Name:
clofarabine

Designated Indication:
Treatment of acute lymphoblastic leukemia

Trade Name (if present):
Clofarex

Date Designated 2/7/2002
Date Approved

Sponsor Contact Information
Ilex Products, Inc.
4545 Horizon Hill Blvd.
San Antonio TX 78229-2263

Generic Name:
Cetuximab

Designated Indication:

Treatment of squamous cell cancer of the head and neck in patients who express epidermal growth factor receptor

Trade Name (if present):

Date Designated 7/3/2000
Date Approved

Sponsor Contact Information

ImClone Systems Incorporated
Branchburg Corporate Center
22 Chubb Way
Somerville NJ 08876

Generic Name:
Cryptosporidium hyperimmune bovine colostrum
IgG concentrate

Designated Indication:

Treatment of diarrhea in AIDS patients caused by infection with Cryptosporidium parvum

Trade Name (if present):

Date Designated 12/30/1991
Date Approved

Sponsor Contact Information

Immucell Corporation
56 Evergreen Drive
Portland ME 04103

Generic Name:
Mitoxantrone

Designated Indication:

Treatment of progressive-relapsing multiple sclerosis.

Trade Name (if present):

Novantrone

Date Designated 8/13/1999
Date Approved 10/13/2000

Sponsor Contact Information

Immunex Corporation
51 University St.
Seattle WA 98101

Generic Name:
Mitoxantrone

Designated Indication:

Treatment of secondary-progressive multiple sclerosis.

Trade Name (if present):

Novantrone

Date Designated 8/13/1999
Date Approved 10/13/2000

Sponsor Contact Information

Immunex Corporation
51 University St.
Seattle WA 98101

Generic Name:
Etanercept

Designated Indication:

Treatment of Wegener's granulomatosis.

Trade Name (if present):

Enbrel

Date Designated 4/6/1999
Date Approved

Sponsor Contact Information

Immunex Corporation
51 University Street
Seattle WA 98101-2936

Generic Name:
Etanercept

Trade Name (if present):
Enbrel

Date Designated 10/27/1998
Date Approved 5/27/1999

Designated Indication:

Reduction in signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs

Sponsor Contact Information

Immunex Corporation
51 University St
Seattle WA 98101-2936

Generic Name:
Sargramostim

Trade Name (if present):
Leukine

Date Designated 3/6/1995
Date Approved 9/15/1995

Designated Indication:

To reduce neutropenia and leukopenia and decrease the incidence of death due to infection in patients with acute myelogenous leukemia.

Sponsor Contact Information

Immunex Corporation
51 University Street
Seattle WA 98101

Generic Name:
Sargramostim

Trade Name (if present):
Leukine

Date Designated 5/3/1990
Date Approved 3/5/1991

Designated Indication:

Treatment of neutropenia associated with bone marrow transplant, for the treatment of graft failure and delay of engraftment, and for the promotion of early engraftment

Sponsor Contact Information

Immunex Corporation
51 University Street
Seattle WA 98101

Generic Name:
Leucovorin

Trade Name (if present):
Leucovorin calcium

Date Designated 8/17/1988
Date Approved 8/31/1988

Designated Indication:

For rescue use after high dose methotrexate therapy in the treatment of osteosarcoma.

Sponsor Contact Information

Immunex Corporation
51 University Street
Seattle WA 98101

Generic Name:
Leucovorin

Trade Name (if present):
Leucovorm calcium

Date Designated 12/8/1986
Date Approved 12/12/1991

Designated Indication:

For use in combination with 5-fluorouracil for the treatment of metastatic colorectal cancer.

Sponsor Contact Information

Immunex Corporation
51 University Street
Seattle WA 98101

Generic Name:
Benzoate and phenylacetate

Trade Name (if present):
Ucephan

Date Designated 1/21/1986

Date Approved 12/23/1987

Designated Indication:

For adjunctive therapy in the prevention and treatment of hyperammonemia in patients with urea cycle enzymopathy due to carbamylphosphate synthetase, ornithine, transcarbamylase, or argininosuccinate synthetase deficiency.

Sponsor Contact Information

Immunex
2525 McGaw Avenue
Immunex

P O Box 19791
Irvine CA 92623

Generic Name:
Protein C concentrate

Trade Name (if present):
Protein C Concentrate (human) Vapor

Date Designated 6/19/1992

Date Approved

Designated Indication:

For replacement therapy in patients with congenital or acquired protein C deficiency for the prevention and treatment of warfarin-induced skin necrosis during oral anticoagulation

Sponsor Contact Information

Immuno Clinical Research Corp
750 Lexington Avenue, 19th Floor
New York NY 10022

Generic Name:
muramyltripeptide, phosphatidyl-ethanolamine
encased in multi-lamellar liposomes

Designated Indication:
Treatment of children and adolescent osteosarcoma

Trade Name (if present):

Date Designated 6/5/2001
Date Approved

Sponsor Contact Information

Immuno-Designed Molecules
9 Parker
Irvine CA 92618-1605

Generic Name:
Ricin (blocked) conjugated murine monoclonal antibody (CD6)

Designated Indication:
Treatment of cutaneous T-cell lymphomas, acute T-cell leukemia-lymphoma, and related mature T-cell malignancies.

Trade Name (if present):

Date Designated 9/6/1994
Date Approved

Sponsor Contact Information

ImmunoGen, Inc.
148 Sidney Street
Cambridge MA 02139

Generic Name:
Ricin (blocked) conjugated murine MCA (n901)

Designated Indication:
Treatment of small cell lung cancer

Trade Name (if present):

Date Designated 1/25/1991
Date Approved

Sponsor Contact Information

ImmunoGen, Inc
148 Sidney Street
Cambridge MA 02139

Generic Name:
Ricin (blocked) conjugated murine mca (anti-b4)

Designated Indication:
For the ex-vivo purging of leukemic cells from the bone marrow of non-T cell acute lymphocytic leukemia patients who are in complete remission

Trade Name (if present):

Date Designated 1/24/1991
Date Approved

Sponsor Contact Information
ImmunoGen, Inc.
148 Sidney Street
Cambridge MA 02139

Generic Name:
Ricin (blocked) conjugated murine MCA (anti-my9)

Designated Indication:
For use in the ex-vivo treatment of autologous bone marrow and subsequent reinfusion in patients with acute myelogenous leukemia

Trade Name (if present):

Date Designated 2/1/1990
Date Approved

Sponsor Contact Information
ImmunoGen, Inc
148 Sidney Street
Cambridge MA 02139

Generic Name:
Ricin (blocked) conjugated murine MCA (anti-my9)

Designated Indication:
Treatment of myeloid leukemia, including AML, and blast crisis of CML

Trade Name (if present):

Date Designated 8/3/1989
Date Approved

Sponsor Contact Information
ImmunoGen, Inc
148 Sidney Street
Cambridge MA 02139

Generic Name:
Ricin (blocked) conjugated murine MCA (anti-B4)

Designated Indication:
Treatment of B-cell leukemia and B-cell lymphoma

Trade Name (if present):

Date Designated 11/17/1988
Date Approved

Sponsor Contact Information
ImmunoGen, Inc.
148 Sidney Street
Cambridge MA 02139

Generic Name:
epratuzumab

Designated Indication:
Treatment of non-Hodgkin's lymphoma.

Trade Name (if present):
LymphoCIDE

Date Designated 7/13/1998
Date Approved

Sponsor Contact Information
Immunomedicas, Inc.
300 American Road
Morris Plains NJ 07950

Generic Name:
Yttrium-90 radiolabeled humanized monoclonal
anti-carcinoembryonic antigen IgG antibody

Trade Name (if present):
Cea-Cide

Date Designated 8/3/1999
Date Approved

Designated Indication:
Treatment of ovarian carcinoma

Generic Name:
MN14 monoclonal antibody to carcinoembryonic
antigen

Trade Name (if present):
Cea-Cide

Date Designated 11/24/1998
Date Approved

Designated Indication:
Treatment of pancreatic cancer.

Generic Name:
MN14 monoclonal antibody to carcinoembryonic
antigen

Trade Name (if present):
Cea-Cide

Date Designated 9/18/1998
Date Approved

Designated Indication:
For the treatment of small cell lung cancer

Generic Name:
Arcitumomab

Trade Name (if present):
99m Tc-labeled CEA-Scan

Date Designated 5/10/1996
Date Approved

Designated Indication:
Diagnosis and localization of primary, residual, recurrent and metastatic
medullary thyroid carcinoma.

Sponsor Contact Information
Immunomedics, Inc.
300 American Road
Morris Plains NJ 07950

Generic Name:
Technetium Tc99m murine monoclonal antibody
(IgG2a) to B cell

Trade Name (if present):
LymphoScan

Date Designated 4/7/1992
Date Approved

Designated Indication:
Diagnostic imaging in the evaluation of the extent of disease in patients with
histologically confirmed diagnosis of non-Hodgkin's B-cell lymphoma, acute B-
cell lymphoblastic leukemia (in children and adults), and chronic B-cell
lymphocytic leukemia.

Sponsor Contact Information
Immunomedics, Inc.
300 American Road
Morris Plains NJ 07950

Generic Name:
Iodine I 131 murine monoclonal antibody IgG2a
to B cell

Trade Name (if present):
Immuraid, I-131-I-131

Date Designated 9/18/1989
Date Approved

Designated Indication:
Treatment of B-cell leukemia and B-cell lymphoma

Sponsor Contact Information
Immunomedics, Inc
300 American Road
Morris Plains NJ 07950

Generic Name:
Technetium Tc99m murine monoclonal antibody
to human alpha-fetoprotein

Trade Name (if present):
Immuraid, AFP-Scan

Date Designated 8/1/1989
Date Approved

Designated Indication:
Detection of hepatocellular carcinoma and hepatoblastoma

Sponsor Contact Information
Immunomedics, Inc
300 American Road
Morris Plains NJ 07950

Generic Name:
Technetium Tc99m murine monoclonal antibody
to human AFP

Trade Name (if present):
AFP-Scan

Date Designated 8/1/1989
Date Approved

Designated Indication:
Detection of alpha-fetoprotein producing germ cell tumors

Sponsor Contact Information
Immunomedics, Inc.
300 American Road
Morris Plains NJ 07950

Generic Name:
Technetium Tc99m murine monoclonal antibody
to hCG

Trade Name (if present):
Immuraid, hCG-Tc-99m

Date Designated 8/7/1989
Date Approved

Designated Indication:
Detection of hCG producing tumors such as germ cell and trophoblastic cell tumors.

Sponsor Contact Information
Immunomedics, Inc.
300 American Road
Morris Plains NJ 07950

Generic Name:
Iodine I 123 murine monoclonal antibody to
alpha-fetoprotein

Trade Name (if present):

Date Designated 9/30/1988
Date Approved

Designated Indication:
Detection of hepatocellular carcinoma and hepatoblastoma

Sponsor Contact Information
Immunomedics, Inc.
300 American Road
Morris Plains NJ 07950

Generic Name:
Iodine I 123 murine monoclonal antibody to alpha-fetoprotein

Trade Name (if present):

Date Designated 9/30/1988
Date Approved

Designated Indication:
Detection of alpha-fetoprotein producing germ cell tumors

Sponsor Contact Information
Immunomedics, Inc.
300 American Road
Morris Plains NJ 07950

Generic Name:
Iodine I 131 murine monoclonal antibody to hCG

Trade Name (if present):

Date Designated 11/7/1988
Date Approved

Designated Indication:
Treatment of hCG producing tumors such as germ cell and trophoblastic cell tumors.

Sponsor Contact Information
Immunomedics, Inc.
300 American Road
Morris Plains NJ 07950

Generic Name:
Iodine I 131 murine monoclonal antibody to alpha-fetoprotein

Trade Name (if present):

Date Designated 9/30/1988
Date Approved

Designated Indication:
Treatment of hepatocellular carcinoma and hepatoblastoma

Sponsor Contact Information
Immunomedics, Inc.
300 American Road
Morris Plains NJ 07950

Generic Name:
Iodine I 131 murine monoclonal antibody to alpha-fetoprotein

Trade Name (if present):

Date Designated 9/30/1988
Date Approved

Designated Indication:
Treatment of alpha-fetoprotein producing germ cell tumors

Sponsor Contact Information
Immunomedics, Inc.
300 American Road
Morris Plains NJ 07950

Generic Name:
Iodine I 123 murine monoclonal antibody to hCG

Trade Name (if present):

Date Designated 11/7/1988
Date Approved

Designated Indication:
Detection of hCG producing tumors such as germ cell and trophoblastic cell tumors.

Sponsor Contact Information
Immunomedics, Inc.
300 American Road
Morris Plains NJ 07950

Generic Name:
Disaccharide tripeptide glycerol dipalmitoyl

Trade Name (if present):
Immther

Date Designated 3/1/1990
Date Approved

Designated Indication:
Treatment of pulmonary and hepatic metastases in patients with colorectal adenocarcinoma

Sponsor Contact Information
ImmunoTherapeutics, Inc.
3505 Riverview Circle
Moorhead MN 56560

Generic Name:
Baclofen

Trade Name (if present):

Date Designated 12/16/1991
Date Approved

Designated Indication:
Treatment of intractable spasticity due to multiple sclerosis or spinal cord injury.

Sponsor Contact Information
InfusaId, Inc.
1400 Providence Highway
Norwood MA 02062

Generic Name:
INH-A00021

Trade Name (if present):
Veronate

Date Designated 6/13/2001
Date Approved

Designated Indication:
Reduction (prevention) of nosocomial bacteremia caused by staphylococci in very low birth weight infants.

Sponsor Contact Information
Inhibitex, Inc
8995 Westside Parkway
Suite 150
Alpharetta GA 30004

Generic Name:
Medroxyprogesterone acetate

Designated Indication:
Treatment of immune thrombocytopenic purpura

Trade Name (if present):
Hematrol

Date Designated 2/22/2001
Date Approved

Sponsor Contact Information
InKine Pharmaceutical Company, Inc.
1787 Sentry Parkway West
Building 18, Suite 440
Blue Bell PA 19422

Generic Name:
Elcatonin

Trade Name (if present):

Date Designated 9/25/1995
Date Approved

Designated Indication:
Intrathecal treatment of intractable pain

Sponsor Contact Information
Innapharma, Inc
10 Mountainview Road
Upper Saddle River NJ 07458

Generic Name:
Nitric oxide

Designated Indication:
Treatment of acute respiratory distress syndrome in adults

Trade Name (if present):

Date Designated 7/10/1995
Date Approved

Sponsor Contact Information
INO Therapeutics, Inc.
54 Old Highway 22
Clinton NJ 08809

Generic Name:
Nitric oxide

Designated Indication:
Treatment of persistent pulmonary hypertension in the newborn

Trade Name (if present):
INOmax

Date Designated 6/22/1993
Date Approved 12/23/1999

Sponsor Contact Information
INO Therapeutics, Inc.
54 Old Highway 22
Clinton NJ 08809

Generic Name:
2-0-Butyryl-1-0-octyl-myo-inositol 3,4,5,6-tetrakisphosphate

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):

Date Designated 8/15/2003
Date Approved

Sponsor Contact Information
Inologic, Inc
101 Elliott Ave., West
Seattle WA 98119

Generic Name:
rhIGF-I/rhIGFBP-3

Designated Indication:
Treatment of extreme insulin resistance syndromes (type A, Rabson-Mendenhall syndrome, Leprechaunism, Type B syndrome)

Trade Name (if present):
SomatoKine

Date Designated 12/9/2003
Date Approved

Sponsor Contact Information
Insmed Inc.
4851 Lake Brooke Drive
Glen Allen VA 23060

Generic Name:
p1-(uridine 5')-p4-(2'-deoxycytidine 5') tetraphosphate, tetrasodium salt

Designated Indication:
For the treatment of cystic fibrosis

Trade Name (if present):

Date Designated 3/7/2001
Date Approved

Sponsor Contact Information
Inspire Pharmaceuticals, Inc.
4222 Emperor Blvd.
Suite 470
Durham NC 27703

Generic Name:
conjugate of human transferrin and a mutant diphtheria toxin (CRM 107)

Trade Name (if present):
TransMID

Date Designated 12/3/2001
Date Approved

Designated Indication:
Treatment of malignant tumors of the central nervous system

Sponsor Contact Information
INTELLgene Expressions Inc
Edmonton Research Park
1938-94 St

CANADA

Generic Name:
Interferon gamma-1b

Trade Name (if present):
Actimmune

Date Designated 9/30/1996
Date Approved 2/10/2000

Designated Indication:
Delaying time to disease progression in patients with severe, malignant osteopetrosis

Sponsor Contact Information
InterMune , Inc.
3280 Bayshore Boulevard
Brisbane CA 94005

Generic Name:
interferon gamma-1b

Trade Name (if present):
Actimmune

Date Designated 9/12/2002
Date Approved

Designated Indication:
Treatment of idiopathic pulmonary fibrosis

Sponsor Contact Information
InterMune, Inc.
3280 Bayshore Boulevard
Brisbane CA 94005

Generic Name:
Interferon gamma 1-b

Trade Name (if present):
Actimmune

Date Designated 9/30/1988
Date Approved 12/20/1990

Designated Indication:
Treatment of chronic granulomatous disease.

Sponsor Contact Information
InterMune, Inc.
3280 Bayshore Blvd
Brisbane CA 94005

Generic Name:
liposomal p-ethoxy growth receptor bound protein-2 antisense product

Trade Name (if present):
Actimmune

Date Designated 12/5/2003
Date Approved

Designated Indication:
Treatment of chronic myelogenous leukemia

Sponsor Contact Information
Interpath Pharmaceuticals, INC
20651 Prince Creek Dr
Katy TX 77450

Generic Name:
Cascara sagrada fluid extract

Designated Indication:
Treatment of oral drug overdosage to speed lower bowel evacuation.

Trade Name (if present):

Date Designated 3/21/1989
Date Approved

Sponsor Contact Information
Intramed Corporation
102 Tremont Way
Augusta GA 30907

Generic Name:
INGN 201

Designated Indication:
Treatment of head and neck cancer

Trade Name (if present):
ADVEXIN

Date Designated 1/27/2003
Date Approved

Sponsor Contact Information
Introgen Therapeutics, Inc.
2250 Holcombe Blvd
Houston TX 77030

Generic Name:
Mitomycin-C

Designated Indication:
Treatment of refractory glaucoma as an adjunct to ab externo glaucoma surgery

Trade Name (if present):

Date Designated 8/20/1993
Date Approved

Sponsor Contact Information
IOP Inc
3100 Airway Avenue, Suite 106
Costa Mesa CA 92626

Generic Name:
Botulinum toxin type A

Designated Indication:
Treatment of dynamic muscle contractures in pediatric cerebral palsy patients.

Trade Name (if present):
Dysport

Date Designated 10/20/1999
Date Approved

Sponsor Contact Information
Ipsen Limited
1 Bath Rd., Maidenhead
Berkshire SL6 4UH

UNITED KINGDOM

Generic Name:
Botulinum toxin type A

Designated Indication:
Treatment of spasmotic torticollis (cervical dystonia).

Trade Name (if present):
Dysport

Date Designated 8/12/1998
Date Approved

Sponsor Contact Information
Ipsen Limited
1 Bath Road
Maidenhead
Berkshire, SL6 4UH
UNITED KINGDOM

Generic Name:
Botulinum toxin type F

Designated Indication:
Treatment of spasmotic torticollis (cervical dystonia).

Trade Name (if present):

Date Designated 10/24/1991
Date Approved

Sponsor Contact Information
Ipsen Limited
27 Maple Street
Milford MA 01757-3650

Generic Name:
Botulinum toxin type F

Designated Indication:
Treatment of essential blepharospasm

Trade Name (if present):

Date Designated 12/5/1991
Date Approved

Sponsor Contact Information
Ipsen Limited (name changed from Porton International Inc)
27 Maple Street
Milford MA 01757

Generic Name:
Lanreotide, Somatostatin

Designated Indication:
Treatment for acromegaly

Trade Name (if present):
Ipstyl

Date Designated 9/11/2000
Date Approved

Sponsor Contact Information
IPSEN, Inc.
27 Maple Street
Milford MA 01757

Generic Name:
Aminosalicylic acid

Designated Indication:
Treatment of tuberculosis infections

Trade Name (if present):
Paser Granules

Date Designated 2/19/1992
Date Approved 6/30/1994

Sponsor Contact Information
Jacobus Pharmaceutical Company
37 Cleveland Lane
P.O. Box 5290
Princeton NJ 08540

Generic Name:
Dapsone USP

Designated Indication:
Prophylaxis for *Pneumocystis carinii* pneumonia.

Trade Name (if present):
Dapsone

Date Designated 12/24/1991
Date Approved

Sponsor Contact Information
Jacobus Pharmaceutical Company
37 Cleveland Lane
P O. Box 5290
Princeton NJ 08540

Generic Name:
Dapsone USP

Designated Indication:

For the combination treatment of Pneumocystis carinii pneumonia in conjunction with trimethoprim

Trade Name (if present):
Dapsone

Date Designated 1/8/1992
Date Approved

Sponsor Contact Information

Jacobus Pharmaceutical Company
37 Cleveland Lane
P O. Box 5290
Princeton NJ 08540

Generic Name:
Sulfapyridine

Designated Indication:

Treatment of dermatitis herpetiformis

Trade Name (if present):

Date Designated 9/10/1990
Date Approved

Sponsor Contact Information

Jacobus Pharmaceutical Company
37 Cleveland Lane
P.O. Box 5290
Princeton NJ 08540

Generic Name:
3,4-diaminopyridine

Designated Indication:

Treatment of Lambert-Eaton myasthenic syndrome

Trade Name (if present):

Date Designated 12/18/1990
Date Approved

Sponsor Contact Information

Jacobus Pharmaceutical Company
37 Cleveland Avenue
P O Box 5290
Princeton NJ 08540

Generic Name:
Dapsone

Designated Indication:

Prophylaxis of toxoplasmosis in severely immunocompromised patients with CD4 counts below 100.

Trade Name (if present):

Date Designated 11/7/1994
Date Approved

Sponsor Contact Information

Jacobus Pharmaceutical Company, Inc.
37 Cleveland Lane
P O. Box 5290
Princeton NJ 08540

Generic Name:
Flunarizine

Designated Indication:

Treatment of alternating hemiplegia.

Trade Name (if present):
Sibelium

Date Designated 1/6/1986
Date Approved

Sponsor Contact Information

Janssen Research Foundation
P.O. Box 200
Titusville NJ 08560

Generic Name:
conjugated bile acids

Designated Indication:
Treatment of steatorrhea in patients with short bowel syndrome

Trade Name (if present):
COBARTin

Date Designated 7/18/2003
Date Approved

Sponsor Contact Information
Jarrow Formulas, Inc.
1824 S. Robertson Blvd.
Los Angeles CA 90035-4317

Generic Name:
Icatibant

Designated Indication:
Treatment of angioedema

Trade Name (if present):

Date Designated 11/25/2003
Date Approved

Sponsor Contact Information
Jerini AG
Invalidenstr 130
10115 Berlin

GERMANY

Generic Name:
Epoetin alfa

Designated Indication:
Treatment of myelodysplastic syndrome.

Trade Name (if present):

Date Designated 12/20/1993
Date Approved

Sponsor Contact Information
Johnson & Johnson Pharmaceutical Research & Dev ,
920 U S Highway
Route 202, P O Box 300
Raritan NJ 08869-0602

Generic Name:
Cladribine

Designated Indication:
Treatment of acute myeloid leukemia

Trade Name (if present):

Leustatin

Date Designated 7/20/1990
Date Approved

Sponsor Contact Information
Johnson & Johnson Pharmaceutical Research & Dev , LLC
920 US Highway 202
P O Box 300
Raritan NJ 08869

Generic Name:
Aminosidine

Designated Indication:
Treatment of visceral leishmaniasis (kala-azar).

Trade Name (if present):

Paromomycin

Date Designated 9/9/1994
Date Approved

Sponsor Contact Information
Kanyok, Thomas P. Pharm D.
University of Illinois at Chicago College of Pharm
833 South Wood Street (m/c886) Rm 176
Chicago IL 60612

Generic Name:
Aminosidine

Designated Indication:
Treatment of Mycobacterium avium complex.

Trade Name (if present):
Gabbromicina

Sponsor Contact Information

Date Designated 11/15/1993
Date Approved

Kanyok, Thomas P. Pharm D.
University of Illinois at Chicago College of Pharm
833 South Wood Street (m/c886) Rm. 176
Chicago IL 60612

Generic Name:
Aminosidine

Designated Indication:
Treatment of tuberculosis

Trade Name (if present):
Gabbromicina

Sponsor Contact Information

Date Designated 5/14/1993
Date Approved

Kanyok, Thomas P. Pharm D.
University Of Illinois At Chicago College of Pharm
833 South Wood Street (m/c886) Rm. 176
Chicago IL 60612

Generic Name:
Tyloxapol

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):
Supervent

Sponsor Contact Information

Date Designated 3/8/1995
Date Approved

Kennedy & Hoidal, M.D.'s
University of Utah Health Sciences Center
50 North Medical Drive, Room 4R240
Salt Lake City UT 84132-0001

Generic Name:
2-O-desulfated heparin

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):
Aeropin

Sponsor Contact Information

Date Designated 9/17/1993
Date Approved

Kennedy & Hoidal, M.D.'s
University of Utah Health Sciences Center
50 North Medical Drive, Room 4R240
Salt Lake City UT 84132

Generic Name:
Dextran sulfate (inhaled, aerosolized)

Designated Indication:
For use as an adjunct to the treatment of cystic fibrosis

Trade Name (if present):
Uendex

Sponsor Contact Information

Date Designated 10/5/1990
Date Approved

Kennedy & Hoidal, M.D.'s
University Of Utah Medical Center
50 North Medical Drive, Room 4R240
Salt Lake City UT 84132

Generic Name:
Reviparin sodium

Trade Name (if present):
Clivarine

Date Designated 6/18/2001
Date Approved

Designated Indication:

Long-term treatment of acute deep vein thrombosis with or without pulmonary embolism in pregnant patients

Sponsor Contact Information
Knoll AG
Ludwigshafen

GERMANY

Generic Name:
Reviparin sodium

Trade Name (if present):
Clivarine

Date Designated 6/18/2001
Date Approved

Designated Indication:

Treatment of deep vein thrombosis which may lead to pulmonary embolism in pediatric patients

Sponsor Contact Information
Knoll AG
Ludwigshafen

GERMANY

Generic Name:
Ancrod

Trade Name (if present):
Viprimex

Date Designated 10/20/1989
Date Approved

Designated Indication:

To establish and maintain anticoagulation in heparin-intolerant patients undergoing cardiopulmonary bypass

Sponsor Contact Information
Knoll Pharmaceutical Company
3000 Continental Dr., North
Mt. Olive NJ 07828

Generic Name:
Anti-CEA Sheep-human chimeric monoclonal antibody labeled w/iodine-131 (KAb201)

Trade Name (if present):

Date Designated 5/21/2003
Date Approved

Designated Indication:
Treatment of pancreatic cancer

Sponsor Contact Information
KS Biomedix Ltd
Ground Floor, 1 Occam Court
Surrey Research Park
GU2 7HJ
UNITED KINGDOM

Generic Name:
Abetimus

Trade Name (if present):

Date Designated 7/28/2000
Date Approved

Designated Indication:
Treatment of lupus nephritis.

Sponsor Contact Information
La Jolla Pharmaceutical Co.
6455 Nancy Ridge Dr
San Diego CA 92121

Generic Name:

Tiratricol

Designated Indication:

For use in combination with levo-thyroxine to suppress thyroid stimulating hormone in patients with well-differentiated thyroid cancer who are intolerant to adequate doses of levo-thyroxine alone.

Trade Name (if present):

Triacana

Sponsor Contact Information

Laphal Laboratoires
48 Bis, Rue des Belles-Feuilles
75116 Paris
FRANCE

Date Designated 8/13/1991**Date Approved****Generic Name:**

a-Galactosidase A

Designated Indication:

Treatment of Fabry's disease

Trade Name (if present):

Plant-Produced Human a-Galactosidase A

Sponsor Contact Information

Large Scale Biology Corporation
3333 Vacaville Parkway
Suite 1000
Vacaville CA 95688

Date Designated 1/21/2003**Date Approved****Generic Name:**

2-chloroethyl-3-sarcosinamide-1-nitrosourea

Designated Indication:

Treatment for malignant gliomas

Trade Name (if present):**Date Designated** 8/3/2001**Date Approved****Sponsor Contact Information**

Lawrence Panasci, MD
Professor of Medicine, McGill University
3755 Cote Ste Catherine
Montreal, Quebec H3T 1E2
CANADA

Generic Name:

Ethyl eicosapentaenoate

Designated Indication:

Treatment of Huntington's disease.

Trade Name (if present):**Date Designated** 4/6/2000**Date Approved****Sponsor Contact Information**

Laxdale Ltd.
Kings Park House, Laurelhill Business Park
Polmaise Road, Stirling FK7 9JQ
UNITED KINGDOM

Generic Name:

Valine, isoleucine and leucine

Designated Indication:

Treatment of hyperphenylalaninemia

Trade Name (if present):

VIL

Sponsor Contact Information

Leas Research Products
78 Fallon Drive
North Haven CT 06473

Date Designated 1/5/1996**Date Approved**

Generic Name:
L-leucovorin

Designated Indication:

For use in combination chemotherapy with the approved agent 5-fluorouracil in the palliative treatment of metastatic adenocarcinoma of the colon and rectum

Trade Name (if present):
Isovorm

Sponsor Contact Information

Lederle Laboratories
Division of American Cyanamid Company
401 N Middletown Road
Pearl River NY 10965

Generic Name:
L-leucovorin

Designated Indication:

For use in conjunction with high-dose methotrexate in the treatment of osteosarcoma

Trade Name (if present):
Isovorm

Sponsor Contact Information

Lederle Laboratories
Division of American Cyanamid Company
401 N. Middletown Road
Pearl River NY 10965

Generic Name:
Fluorouracil

Designated Indication:

For use in combination with leucovorin for therapy of metastatic adenocarcinoma of the colon and rectum.

Trade Name (if present):
Adrucil

Sponsor Contact Information

Lederle Laboratories
Division of American Cyanamid Company
401 N. Middletown Road
Pearl River NY 10965

Generic Name:
Mitoxantrone HCl

Designated Indication:

Treatment of acute myelogenous leukemia, also referred to as acute nonlymphocytic leukemia

Trade Name (if present):
Novantrone

Sponsor Contact Information

Lederle Laboratories
Division of American Cyanamid Company
401 N. Middletown Road
Pearl River NY 10965

Generic Name:
Methotrexate sodium

Designated Indication:

Treatment of osteogenic sarcoma.

Trade Name (if present):
Methotrexate

Sponsor Contact Information

Lederle Laboratories
Division of American Cyanamid Company
401 N. Middletown Road
Pearl River NY 10965

Generic Name:
24,25 dihydroxycholecalciferol

Designated Indication:
Treatment of uremic osteodystrophy.

Trade Name (if present):

Date Designated 2/27/1987
Date Approved

Sponsor Contact Information
Lemmon Company
1510 Delp Drive
Kulpsville PA 19443

Generic Name:
Zinc acetate

Designated Indication:
Treatment of Wilson's disease.

Trade Name (if present):
Galzin

Date Designated 11/6/1985
Date Approved 1/28/1997

Sponsor Contact Information
Lemmon Company
1510 Delp Drive
Kulpsville PA 19443

Generic Name:
L-cycloserine

Designated Indication:
Treatment of Gaucher's disease.

Trade Name (if present):

Date Designated 8/1/1989
Date Approved

Sponsor Contact Information
Lev, Meir M D.
The City College, City University Of NY Medical Sc
Convent Avenue at 138 Street
New York NY 10031

Generic Name:
Alitretinoin

Designated Indication:
Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.

Trade Name (if present):
Panretin

Date Designated 3/24/1998
Date Approved 2/2/1999

Sponsor Contact Information
Ligand Pharmaceuticals Inc.
10275 Science Center Drive
San Diego CA 92121-1117

Generic Name:
Denileukin diftitox

Designated Indication:
Treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor.

Trade Name (if present):
Ontak

Date Designated 8/21/1996
Date Approved 2/5/1999

Sponsor Contact Information
Ligand Pharmaceuticals Inc
10275 Science Center Drive
San Diego CA 92121

Generic Name:
Bexarotene

Designated Indication:

Treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy

Trade Name (if present):
Targretin

Date Designated 6/18/1999
Date Approved 12/29/1999

Sponsor Contact Information

Ligand Pharmaceuticals, Inc.
10275 Science Center Dr.
San Diego CA 92121

Generic Name:
9-cis retinoic acid

Designated Indication:

Treatment of acute promyelocytic leukemia.

Trade Name (if present):
Panretin

Date Designated 4/10/1992
Date Approved

Sponsor Contact Information

Ligand Pharmaceuticals, Inc.
10275 Science Center Dr.
San Diego CA 92121-1117

Generic Name:
Aconiazide

Designated Indication:

Treatment of tuberculosis

Trade Name (if present):

Date Designated 6/20/1988
Date Approved

Sponsor Contact Information

Lincoln Diagnostics
P O. Box 1128
Decatur IL 62525

Generic Name:
Gentamicin impregnated PMMA beads on surgical wire

Designated Indication:

Treatment of chronic osteomyelitis of post-traumatic, postoperative, or hematogenous origin.

Trade Name (if present):
Septopal

Date Designated 1/31/1991
Date Approved

Sponsor Contact Information

Lipha Pharmaceuticals, Inc
9 West 57th Street
Suite 3825
New York NY 10019-2701

Generic Name:
Amphotericin B lipid complex

Designated Indication:

Treatment of invasive fungal infections.

Trade Name (if present):
Abelcet

Date Designated 12/5/1991
Date Approved 10/18/1996

Sponsor Contact Information

Liposome Company, Inc
One Research Way
Princeton NJ 08540

Generic Name:
Gentamicin liposome injection

Designated Indication:
Treatment of disseminated Mycobacterium avium-intracellulare infection

Trade Name (if present):
Maitec

Date Designated 7/10/1990
Date Approved

Sponsor Contact Information
Liposome Company, Inc.
One Research Way
Princeton NJ 08540

Generic Name:
diphenylcyclopeneone

Designated Indication:
Treatment of chronic severe forms of alopecia areata (Alopecia Totalis [AT]/Alopecia Universalis [AU])

Trade Name (if present):

Date Designated 6/13/2003
Date Approved

Sponsor Contact Information
Lloyd E. King, Jr.
1900 Patterson Street
Suite 104
Nashville TN 37203

Generic Name:
Virulizin

Designated Indication:
Treatment of pancreatic cancer.

Trade Name (if present):
Virulizin

Date Designated 2/1/2001
Date Approved

Sponsor Contact Information
Lorus Therapeutics Inc.
7100 Woodbine Avenue, Suite 215
Markham, ON L3R 5J2

CANADA

Generic Name:
antisense 20-mer phosphorothioate
oligonucleotide [complementary to the coding
region of R2 component of the human
ribonucleotide reductase mRNA]

Designated Indication:
Treatment for renal cell carcinoma

Trade Name (if present):
GTI-2040

Date Designated 3/12/2003
Date Approved

Sponsor Contact Information
Lorus Therapeutics, Inc
2 Meridan Road
Toronto, Ontario

CANADA

Generic Name:
111Indium pentetreotide

Designated Indication:
Treatment of somatostatin receptor positive neuroendocrine tumors.

Trade Name (if present):
SomatoTher

Date Designated 6/10/1999
Date Approved

Sponsor Contact Information
Louisiana State University Medical Center Foundation
1600 Canal St.
10th Floor
New Orleans LA 70112

Generic Name:
Calcium gluconate gel

Designated Indication:
For use in the emergency topical treatment of hydrogen fluoride (hydrofluoric acid) burns

Trade Name (if present):
H-F Gel

Date Designated 5/21/1991
Date Approved

Sponsor Contact Information
LTR Pharmaceuticals, Inc
145 Sakonnet Blvd
Narragansett RI 02882

Generic Name:
Angiotensin 1-7

Designated Indication:
Treatment of myelodysplastic syndrome

Trade Name (if present):
MARstem

Date Designated 8/3/2001
Date Approved

Sponsor Contact Information
Maret Pharmaceutical Corporation
4041 MacArthur Boulevard, Suite 375
Newport Beach CA 92660

Generic Name:
Angiotensin 1-7

Designated Indication:
Treatment of neutropenia associated with autologous bone marrow transplantation.

Trade Name (if present):

Date Designated 2/16/2000
Date Approved

Sponsor Contact Information
Maret Pharmaceuticals
4041 MacArthur Blvd.
Suite 375
Newport Beach CA 92660

Generic Name:
Papain, trypsin, and chymotrypsin

Designated Indication:
Treatment of multiple myeloma

Trade Name (if present):

Wobe-Mugos

Date Designated 12/21/1998
Date Approved

Sponsor Contact Information
Marlyn Nutraceuticals, Inc
14851 N Scottsdale Rd.
Scottsdale AZ 85254

Generic Name:
Cytomegalovirus immune globulin (human)

Designated Indication:
Prevention or attenuation of primary cytomegalovirus disease in immunosuppressed recipients of organ transplants

Trade Name (if present):

CytoGam

Date Designated 8/3/1987
Date Approved 12/4/1998

Sponsor Contact Information
Massachusetts Public Health Biologic Laboratories
305 South Street
Boston MA 02130-3597

Generic Name:
Cisplatin/epinephrine

Designated Indication:
Treatment of metastatic malignant melanoma

Trade Name (if present):
IntraDose

Date Designated 9/7/2000
Date Approved

Sponsor Contact Information
Matrix Pharmaceutical, Inc.
34700 Campus Drive
Fremont CA 94555-3612

Generic Name:
Cisplatin/epinephrine

Designated Indication:
Treatment of squamous cell carcinoma of the head and neck

Trade Name (if present):
IntraDose

Date Designated 4/3/2000
Date Approved

Sponsor Contact Information
Matrix Pharmaceutical, Inc.
34700 Campus Drive
Fremont CA 94555-3612

Generic Name:
Histamine

Designated Indication:
Adjunct to cytokine therapy in the treatment of acute myeloid leukemia

Trade Name (if present):
Maxamime

Date Designated 12/15/1999
Date Approved

Sponsor Contact Information
Maxim Pharmaceuticals, Inc.
8899 University Center Lane
Suite 400
San Diego CA 92122

Generic Name:
Histamine

Designated Indication:
For use as an adjunct to cytokine therapy in the treatment of malignant melanoma.

Trade Name (if present):
Maxamime

Date Designated 2/1/2000
Date Approved

Sponsor Contact Information
Maxim Pharmaceuticals, Inc.
8899 University Center Lane
Suite 400
San Diego CA 92122

Generic Name:
Dynameine

Designated Indication:
Treatment of hereditary motor and sensory neuropathy type I (Charcot-Marie-Tooth disease).

Trade Name (if present):

Date Designated 10/16/1991
Date Approved

Sponsor Contact Information
Mayo Foundation
200 First Street Southwest
Rochester MN 55905

Generic Name:
Dynamine

Designated Indication:
Treatment of Lambert Eaton myasthenic syndrome

Trade Name (if present):

Date Designated 2/5/1990
Date Approved

Sponsor Contact Information
Mayo Foundation
200 First Street Southwest
Rochester MN 55905

Generic Name:
Erythropoietin (recombinant human)

Designated Indication:
Treatment of anemia associated with end stage renal disease

Trade Name (if present):

Date Designated 8/19/1987
Date Approved

Sponsor Contact Information
McDonnell Douglas Corp
P O. Box 516, 107/2 MS10
St Louis MO 63166

Generic Name:
Treasulfan

Designated Indication:
Treatment of ovarian cancer.

Trade Name (if present):

Ovastat

Date Designated 5/16/1994
Date Approved

Sponsor Contact Information
Medac GmbH
Fehlandstrasse 3
D-20354 Hamburg

GERMANY

Generic Name:
Phosphocysteamine

Designated Indication:
Treatment of cystinosis.

Trade Name (if present):

Date Designated 9/12/1988
Date Approved

Sponsor Contact Information
Medea Research Laboratories
Port Jefferson Business Center
200 Wilson Street, Building D-6
Port Jefferson NY 11776

Generic Name:
monarsen

Designated Indication:
Treatment of Myasthenia Gravis

Trade Name (if present):

Date Designated 11/14/2003
Date Approved

Sponsor Contact Information
Medica Venture Partners
Ackerstein Towers, Bldg B, 10th Floor
ISRAEL

ISRAEL

Generic Name:
sodium phenylbutyrate

Trade Name (if present):
Buphenyl

Date Designated 11/22/1993
Date Approved 4/30/1996

Designated Indication:

Treatment of urea cycle disorders carbamylphosphate synthetase deficiency, ornithine transcarbamylase deficiency, and arginosuccinic acid synthetase deficiency

Sponsor Contact Information

Medicis Pharmaceutical Corp.
8125 N Hayden Road
Scottsdale AZ 85258

Generic Name:
benzoate/phenylacetate

Trade Name (if present):
Ammonul

Date Designated 11/22/1993
Date Approved

Designated Indication:

For the treatment of acute hyperammonemia and associated encephalopathy in patients with deficiencies in enzymes of the urea cycle

Sponsor Contact Information

Medicis Pharmaceutical Corp.
8125 N Hayden Road
Scottsdale AZ 85258

Generic Name:
sodium phenylbutyrate

Trade Name (if present):

Date Designated 7/2/1992
Date Approved

Designated Indication:

Treatment for sickling disorders, which include S-S hemoglobinopathy, S-C hemoglobinopathy, and S-thalassemia hemoglobinopathy

Sponsor Contact Information

Medicis Pharmaceutical Corp.
8125 N Hayden Road
Scottsdale AZ 85258

Generic Name:
genetically engineered herpes simplex virus
(G207)

Trade Name (if present):

Date Designated 4/29/2002
Date Approved

Designated Indication:

Treatment of malignant glioma

Sponsor Contact Information

MediGene, Inc.
10660 Scripps Ranch Blvd.
Suite 200
San Diego CA 92131

Generic Name:
Respiratory syncytial virus immune globulin
(Human)

Trade Name (if present):
Respigam

Date Designated 9/27/1990
Date Approved 1/18/1996

Designated Indication:

Prophylaxis of respiratory syncytial virus lower respiratory tract infections in infants and young children at high risk of RSV disease

Sponsor Contact Information

MedImmune & Massachusetts Public Health Biologics Labs.
35 West Watkins Mill Road
Gaithersburg MD 20878

Generic Name:
siplizumab

Designated Indication:
Treatment of T-cell lymphomas

Trade Name (if present):

Date Designated 7/15/2003
Date Approved

Sponsor Contact Information
MedImmune Oncology, Inc.
35 W Watkins Mill Road
Gaithersburg MD 20878

Generic Name:
Trimetrexate

Designated Indication:
Treatment of metastatic osteogenic sarcoma

Trade Name (if present):
Neutrexin

Date Designated 8/10/2000
Date Approved

Sponsor Contact Information
Medimmune Oncology, Inc
One MedImmune Way
Gaithersburg MD 20878

Generic Name:
Amifostine

Designated Indication:
Treatment of myelodysplastic syndromes.

Trade Name (if present):
Ethyol

Date Designated 10/4/1999
Date Approved

Sponsor Contact Information
Medimmune Oncology, Inc
One MedImmune Way
Gaithersburg MD 20878

Generic Name:
Amifostine

Designated Indication:
For the reduction of the incidence and severity of toxicities associated with cisplatin administration.

Trade Name (if present):
Ethyol

Date Designated 11/24/1998
Date Approved

Sponsor Contact Information
Medimmune Oncology, Inc
One MedImmune Way
Gaithersburg MD 20878

Generic Name:
Amifostine

Designated Indication:
Reduction of the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer

Trade Name (if present):
Ethyol

Date Designated 5/12/1998
Date Approved 6/24/1999

Sponsor Contact Information
Medimmune Oncology, Inc.
One Tower Bridge
100 Front Street, Suite 400
Conshohocken PA 19428

Generic Name:
Amifostine

Designated Indication:

For use as a chemoprotective agent for cyclophosphamide in the treatment of advanced ovarian carcinoma.

Trade Name (if present):
Ethyol

Date Designated 5/30/1990
Date Approved

Sponsor Contact Information

Medimmune Oncology, Inc.
One MedImmune Way
Gaithersburg MD 20878

Generic Name:
Amifostine

Designated Indication:

For use as a chemoprotective agent for cisplatin in the treatment of metastatic melanoma

Trade Name (if present):
Ethyol

Date Designated 5/30/1990
Date Approved

Sponsor Contact Information

Medimmune Oncology, Inc.
One MedImmune Way
Gaithersburg MD 20878

Generic Name:
Amifostine

Designated Indication:

For use as a chemoprotective agent for cisplatin in the treatment of advanced ovarian carcinoma

Trade Name (if present):
Ethyol

Date Designated 5/30/1990
Date Approved 12/8/1995

Sponsor Contact Information

Medimmune Oncology, Inc.
One Tower Bridge
100 Front Street, Suite 400
West Conshohocken PA 19428

Generic Name:
Trimetrexate glucuronate

Designated Indication:

Treatment of patients with advanced non-small cell carcinoma of the lung.

Trade Name (if present):

Date Designated 1/13/1988
Date Approved

Sponsor Contact Information

Medimmune Oncology, Inc.
One MedImmune Way
Gaithersburg MD 20878

Generic Name:
Trimetrexate glucuronate

Designated Indication:

Treatment of Pneumocystis carinii pneumonia in AIDS patients.

Trade Name (if present):
Neutrexin

Date Designated 5/15/1986
Date Approved 12/17/1993

Sponsor Contact Information

Medimmune Oncology, Inc.
One Tower Bridge
100 Front Street, Suite 400
West Conshohocken PA 19428

Generic Name:
Trimetrexate glucuronate

Designated Indication:
Treatment of metastatic carcinoma of the head and neck (i.e. buccal cavity, pharynx, and larynx).

Trade Name (if present):

Date Designated 7/25/1985
Date Approved

Sponsor Contact Information
MedImmune Oncology, Inc.
One MedImmune Way
Gaithersburg MD 20878

Generic Name:
Trimetrexate glucuronate

Designated Indication:
Treatment of metastatic colorectal adenocarcinoma.

Trade Name (if present):

Date Designated 7/25/1985
Date Approved

Sponsor Contact Information
MedImmune Oncology, Inc.
One MedImmune Way
Gaithersburg MD 20878

Generic Name:
Trimetrexate glucuronate

Designated Indication:
Treatment of pancreatic adenocarcinoma.

Trade Name (if present):

Date Designated 7/25/1985
Date Approved

Sponsor Contact Information
MedImmune Oncology, Inc.
One MedImmune Way
Gaithersburg MD 20878

Generic Name:
Altretamine

Designated Indication:
Treatment of advanced adenocarcinoma of the ovary.

Trade Name (if present):
Hexalen

Date Designated 2/9/1984
Date Approved 12/26/1990

Sponsor Contact Information
MedImmune Oncology, Inc.
One Tower Bridge
100 Front Street, Suite 400
Conshohocken PA 19428

Generic Name:
Parovirus B19 (recombinant VP1 and VP2;
S.frugiperda cells) vaccine

Designated Indication:
Prevention of transient aplastic crisis in patients with sickle cell anemia.

Trade Name (if present):
MEDI-491

Date Designated 5/7/1999
Date Approved

Sponsor Contact Information
MedImmune, Inc.
35 West Watkins Mill Rd
Gaithersburg MD 20878

Generic Name:
Humanized anti-CD2 monoclonal antibody

Designated Indication:
Treatment of graft-versus-host disease

Trade Name (if present):

Date Designated 11/13/1998
Date Approved

Sponsor Contact Information
MedImmune, Inc.
35 West Watkins Mill Rd
Gaithersburg MD 20878

Generic Name:
Respiratory Syncytial Virus Immune Globulin
(human)

Designated Indication:
Treatment of respiratory syncytial virus lower respiratory tract infections in hospitalized infants and young children

Trade Name (if present):
Hyperimmune RSV

Date Designated 9/27/1990
Date Approved

Sponsor Contact Information
MedImmune, Inc.
35 West Watkins Mill Road
Gaithersburg MD 20878

Generic Name:
debrase

Designated Indication:
Debridement of acute, deep dermal burns in hospitalized patients

Trade Name (if present):
Debridase

Date Designated 8/20/2003
Date Approved

Sponsor Contact Information
MediWound, Ltd.
3, Azrieli Center
Triangular Tower 45th Floor
Tel-Aviv 67023
ISRAEL

Generic Name:
baclofen

Designated Indication:
Treatment of dystonia

Trade Name (if present):

Date Designated 12/2/2003
Date Approved

Sponsor Contact Information
Medtronic Neurological
710 Medtronic Parkway NE
Minneapolis MN 55432-5604

Generic Name:
Baclofen

Designated Indication:
Treatment of spasticity associated with cerebral palsy.

Trade Name (if present):
Lioresal Intrathecal

Date Designated 9/26/1994
Date Approved

Sponsor Contact Information
Medtronic, Inc.
800 53rd Avenue N E.
P O. 1250
Minneapolis MN 55440-9087

Generic Name:
Baclofen

Designated Indication:

Treatment of intractable spasticity caused by spinal cord injury, multiple sclerosis, and other spinal diseases (including spinal ischemia, spinal tumor, transverse myelitis, cervical spondylosis, and degenerative myelopathy).

Trade Name (if present):
Lioresal Intrathecal

Date Designated 11/10/1987
Date Approved 6/25/1992

Sponsor Contact Information

Medtronic, Inc
800 53rd Avenue N E
Minneapolis MN 55432

Generic Name:
Fibronectin (human plasma derived)

Designated Indication:

Treatment of non-healing corneal ulcers or epithelial defects which have been unresponsive to conventional therapy and the underlying cause has been eliminated

Trade Name (if present):

Date Designated 9/5/1988
Date Approved

Sponsor Contact Information

Melville Biologics, Inc.
310 East 67th Street
New York NY 10021

Generic Name:
Mefloquine HCl

Designated Indication:

Treatment of chloroquine-resistant Falciparum malaria

Trade Name (if present):
Mephaquin

Date Designated 7/22/1987
Date Approved

Sponsor Contact Information

Mepha AG
4143 Dornach
POSTFASH 137

SWITZERLAND

Generic Name:
Mefloquine HCl

Designated Indication:

Prevention of chloroquine-resistant Falciparum malaria.

Trade Name (if present):
Mephaquin

Date Designated 7/22/1987
Date Approved

Sponsor Contact Information

Mepha AG
4143 Dornach
POSTFASH 137

SWITZERLAND

Generic Name:
alendronate

Designated Indication:

Treatment of osteogenesis imperfecta in pediatric patients 4 years of age and older

Trade Name (if present):
Fosamax

Date Designated 3/31/2003
Date Approved

Sponsor Contact Information

Merck & Co , Inc.
126 East Lincoln Ave.
Rahway NJ 07065-0900

Generic Name:
Trentine HCl

Trade Name (if present):
Syprine

Date Designated 12/24/1984
Date Approved 11/8/1985

Designated Indication:

Treatment of patients with Wilson's disease who are intolerant, or inadequately responsive to penicillamine

Sponsor Contact Information

Merck Sharp & Dohme Research
Division Of Merck And Company
West Point PA 19486

Generic Name:
Recombinant Human Alpha-Fetoprotein (rhAFP)

Designated Indication:
Treatment of myasthenia gravis

Trade Name (if present):

Date Designated 2/22/2001
Date Approved

Sponsor Contact Information

Merrimack Pharmaceuticals, Inc
101 Binney Street
Cambridge MA 02142

Generic Name:
irofulven

Designated Indication:
Treatment of renal cell carcinoma.

Trade Name (if present):

Date Designated 7/27/1999
Date Approved

Sponsor Contact Information

MGI Pharma, Inc
6300 West Old Shakoppe Rd.
Suite 110
Bloomington MN 55438-2318

Generic Name:
irofulven

Designated Indication:
Treatment of ovarian cancer.

Trade Name (if present):

Date Designated 7/6/1999
Date Approved

Sponsor Contact Information

MGI Pharma, Inc.
5775 West Old Shakoppe Rd.
Suite 100
Bloomington MN 55437-3107

Generic Name:
6-hydroxymethylacylfulvene

Designated Indication:
Treatment of histologically confirmed advanced or metastatic pancreatic cancer

Trade Name (if present):

Date Designated 4/6/1999
Date Approved

Sponsor Contact Information

MGI Pharma, Inc.
6300 West Old Shakoppe Rd.
Suite 110
Bloomington MN 55438-2318

Generic Name:
Pilocarpine HCl

Designated Indication:
Treatment of xerostomia and keratoconjunctivitis sicca in Sjogren's syndrome patients

Trade Name (if present):
Salagen

Date Designated 2/28/1992
Date Approved 2/11/1998

Sponsor Contact Information
MGI Pharma, Inc.
6300 West Old Shakopee Rd
Suite 110
Bloomington MN 55438-2318

Generic Name:
Pilocarpine

Designated Indication:
Treatment of xerostomia induced by radiation therapy for head and neck cancer.

Trade Name (if present):
Salagen

Date Designated 9/24/1990
Date Approved 3/22/1994

Sponsor Contact Information
MGI Pharma, Inc.
6300 West Old Shakopee Rd.
Suite 110
Bloomington MN 55438-2318

Generic Name:
Etidronate disodium

Designated Indication:
Treatment of hypercalcemia of malignancy inadequately managed by dietary modification and/or oral hydration

Trade Name (if present):
Didronel

Date Designated 3/21/1986
Date Approved 4/21/1987

Sponsor Contact Information
MGI Pharma, Inc
6300 West Old Shakopee Rd
Suite 110
Bloomington MN 55438-2318

Generic Name:
Human T-lymphotropic virus type III Gp160
antigens

Designated Indication:
Treatment of AIDS

Trade Name (if present):
Vaxsyn HIV-1

Date Designated 11/20/1989
Date Approved

Sponsor Contact Information
MicroGeneSys, Inc.
1000 Research Parkway
Meriden CT 06450

Generic Name:
alemtuzumab

Designated Indication:
Treatment of chronic lymphocytic leukemia.

Trade Name (if present):
Campath

Date Designated 10/20/1997
Date Approved 5/7/2001

Sponsor Contact Information
Millennium and ILEX Partners, LP
75 Sidney Street
Cambridge MA 02138

Generic Name:
bortezomib

Designated Indication:
To treat multiple myeloma

Trade Name (if present):
VELCADE

Date Designated 1/15/2003
Date Approved 5/13/2003

Sponsor Contact Information
Millennium Pharmaceuticals, Inc
75 Sidney Street
Cambridge MA 02139

Generic Name:
tin ethyl etiopurpurin

Designated Indication:
Prevention of access graft disease in hemodialysis patients

Trade Name (if present):

Date Designated 11/4/2003
Date Approved

Sponsor Contact Information
Miravant Medical Technologies
336 Bollay Drive
Goleta CA 93117

Generic Name:
Prostaglandin E1 enol ester (AS-013)

Designated Indication:
Treatment of Fontaine Stage IV chronic critical limb ischemia.

Trade Name (if present):

Date Designated 6/12/1998
Date Approved

Sponsor Contact Information
Mitsubishi Pharma America, Inc.
25 Independence Blvd , Suite 201
Warren NJ 07059

Generic Name:
Duramycin

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):

Date Designated 12/11/1997
Date Approved

Sponsor Contact Information
MoliChem Medicines Inc.
207 South Elliott Road PMB#231
Chapel Hill NC 27514

Generic Name:
Glyceryl trioleate and glyceryl trierucate

Designated Indication:
Treatment of adrenoleukodystrophy.

Trade Name (if present):

Date Designated 2/14/1995
Date Approved

Sponsor Contact Information
Moser, Hugo W M D.
Johns Hopkins University
Kennedy Krieger Institute, 707 North Broadway
Baltimore MD 21205

Generic Name:
albuterol

Designated Indication:
Prevention of paralysis due to spinal cord injury

Trade Name (if present):

Date Designated 3/12/2002
Date Approved

Sponsor Contact Information
MotoGen, Inc
3 Pine View Road
Mount Kisco NY 10549

Generic Name:
Branched chain amino acids

Designated Indication:
Treatment of amyotrophic lateral sclerosis

Trade Name (if present):

Date Designated 12/23/1988
Date Approved

Sponsor Contact Information
Mount Sinai Medical Center
One Gustave L. Levy Place
New York NY 10029

Generic Name:
Marijuana

Designated Indication:
Treatment of HIV-associated wasting syndrome

Trade Name (if present):

Date Designated 5/25/1999
Date Approved

Sponsor Contact Information
Multidisciplinary Association for Psychedelic Studies, Inc
3 Francis St.
Belmont MA 02478

Generic Name:
Cysteamine

Designated Indication:
Treatment of nephropathic cystinosis.

Trade Name (if present):

Cystagon

Date Designated 1/25/1991
Date Approved 8/15/1994

Sponsor Contact Information
Mylan Laboratories, Inc.
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown WV 26504

Generic Name:
Mafenide acetate solution

Designated Indication:
For use as an adjunctive topical antimicrobial agent to control bacterial infection when used under moist dressings over meshed autografts on excised burn wounds

Trade Name (if present):

Sulfamylon solution

Date Designated 7/18/1990
Date Approved 6/5/1998

Sponsor Contact Information
Mylan Laboratories, Inc.
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown WV 26504-4310

Generic Name:
Apomorphine HCl

Designated Indication:
Treatment of the on-off fluctuations associated with late-stage Parkinson's disease

Trade Name (if present):
Apokyn

Date Designated 4/22/1993
Date Approved

Sponsor Contact Information
Mylan Pharmaceuticals, Inc.
781 Chestnut Ridge Rd.
PO Box 4310
Morgantown WV 26505-4310

Generic Name:
Hepatitis B immune globulin intravenous
(human)

Designated Indication:
Prophylaxis against hepatitis B virus reinfection in liver transplant patients

Trade Name (if present):
Nabi-HB

Date Designated 3/8/1995
Date Approved

Sponsor Contact Information
NABI
12280 Wilkins Avenue
Rockville MD 20852

Generic Name:
Hepatitis C virus immune globulin (human)

Designated Indication:
Prophylaxis of hepatitis C infection in liver transplant recipients.

Trade Name (if present):

Date Designated 11/14/2002
Date Approved

Sponsor Contact Information
NABI
5800 Park of Commerce Blvd , N W.
Boca Raton FL 33487

Generic Name:
N-acetyl-procainamide

Designated Indication:
Prevention of life-threatening ventricular arrhythmias in patients with documented procainamide-induced lupus

Trade Name (if present):

Date Designated 12/10/1996
Date Approved

Sponsor Contact Information
NAPA of the Bahamas
3560 Pennsylvania Avenue, Suite 7
Dubuque IA 52002

Generic Name:
Zalcitabine

Designated Indication:
Treatment of AIDS.

Trade Name (if present):

Date Designated 12/9/1986
Date Approved

Sponsor Contact Information
National Cancer Institute, DCT
NIH, Executive Plaza North, Room 7-18
Bethesda MD 20892

Generic Name:
Alpha-melanocyte stimulating hormone

Designated Indication:
Prevention and treatment of intrinsic acute renal failure due to ischemia.

Trade Name (if present):

Date Designated 8/19/1997
Date Approved

Sponsor Contact Information
National Institute of Diabetes, and Digestive and Kidney Diseases
National Institutes of Health, 31 Center Drive MSC
Building 31, Room 9N-222
Bethesda MD 20892-2560

Generic Name:
PEG-glucocerebrosidase

Designated Indication:
For use as chronic enzyme replacement therapy in patients with Gaucher's disease who are deficient in glucocerebrosidase

Trade Name (if present):
Lysodase

Date Designated 12/9/1992
Date Approved

Sponsor Contact Information
National Institute of Mental Health, NIH
49 Convent Dr. MSC4405
Bldg. 49, Room B1EE16
Bethesda MD 20892-4405

Generic Name:
SS1(dsFv)-PE38

Designated Indication:
Treatment of malignant mesothelioma

Trade Name (if present):

Date Designated 2/11/2002
Date Approved

Sponsor Contact Information
NeoPharm Incorporated
150 Field Drive
Suite 195
Lake Forest IL 60045

Generic Name:
SS1(dsFv)-PE38

Designated Indication:
Treatment of epithelial ovarian cancer

Trade Name (if present):

Date Designated 2/11/2002
Date Approved

Sponsor Contact Information
NeoPharm, Inc.
150 Field Drive
Suite 195
Lake Forest IL 60045

Generic Name:
IL13-PE38QQR

Designated Indication:
Treatment of malignant glioma

Trade Name (if present):

Date Designated 11/2/2001
Date Approved

Sponsor Contact Information
NeoPharm, Inc.
150 Field Drive
Suite 195
Lake Forest IL 60045

Generic Name:
Iodoxuridine

Designated Indication:
Treatment of nonparenchymatous sarcomas

Trade Name (if present):

Date Designated 4/8/1996
Date Approved

Sponsor Contact Information
NeoPharm, Inc.
225 East Deerpath, Suite 250
Lake Forest IL 60045

Generic Name:
Broxuridine

Designated Indication:
Radiation sensitizer in the treatment of primary brain tumors

Trade Name (if present):
Broxine/Neomark

Date Designated 9/18/1995
Date Approved

Sponsor Contact Information
NeoPharm, Inc.
225 East Deerpath, Suite 250
Lake Forest IL 60045

Generic Name:
166Ho-DOTMP

Designated Indication:
Treatment of multiple myeloma

Trade Name (if present):

Date Designated 2/10/1999
Date Approved

Sponsor Contact Information
NeoRx Corporation
410 W. Harrison Street
Seattle WA 98119-4007

Generic Name:
Corticotropin-releasing factor, human

Designated Indication:
Treatment of peritumoral brain edema

Trade Name (if present):

Xerecept

Date Designated 4/6/1998
Date Approved

Sponsor Contact Information
Neurobiological Technologies, Inc.
1387 Marina Way South
Richmond CA 94804

Generic Name:
Sodium 1,3-propanedisulfonate

Designated Indication:
Treatment of secondary amyloidosis

Trade Name (if present):

Date Designated 4/6/1999
Date Approved

Sponsor Contact Information
Neurochem, Inc.
7220 Frederick Banting, Suite 100
Saint-Laurent, Quebec H4S 2A1
CANADA

Generic Name:
IL-4 Pseudomonas Toxin Fusion Protein (IL-4(38-37)-PE38KDEL)

Designated Indication:
Treatment of astrocytic glioma

Trade Name (if present):

Date Designated 4/6/2000
Date Approved

Sponsor Contact Information
Neurocrine Biosciences, Inc
10555 Science Center Dr.
San Diego CA 92121

Generic Name:
Capsaicin

Designated Indication:
Treatment of painful HIV-associated neuropathy

Trade Name (if present):

Date Designated 5/2/2003
Date Approved

Sponsor Contact Information
NeurogesX, Inc.
San Carlos Business Park
981F Industrial Road
San Carols CA 94070-4117

Generic Name:
capsaicin

Designated Indication:
Treatment of erythromelalgia

Trade Name (if present):

Date Designated 10/23/2002
Date Approved

Sponsor Contact Information
NeurogesX, Inc.
981F Industrial Road
San Carlos CA 94070

Generic Name:
Leupeptin

Designated Indication:
For use as an adjunct to microsurgical peripheral nerve repair

Trade Name (if present):

Date Designated 9/18/1990
Date Approved

Sponsor Contact Information
Neuromuscular Adjuncts, Inc
S.U.N.Y. at Stony Brook
H.S.C. T18-020
Stony Brook NY 11794-8181

Generic Name:
N-[4-bromo-2-(1H-1,2,3,4-tetrazol-5-yl)phenyl]-
N'-[3,5-bis(trifluoromethyl)phenyl]urea

Designated Indication:
Treatment of sickle cell disease

Trade Name (if present):

Date Designated 5/13/2002
Date Approved

Sponsor Contact Information
NeuroSearch A/S
93 Pederstrupvej
DK-2750 Ballerup

DENMARK

Generic Name:
recombinant human monoclonal antibody to
hsp90

Designated Indication:
Treatment of invasive candidiasis

Trade Name (if present):
Mycograh

Date Designated 9/16/2002
Date Approved

Sponsor Contact Information
NeuTec Pharma plc
2dn floor, Clinical Sciences Bldg.
Central Manchester Healthcare Trust, Oxford Rd , M

Generic Name:
Sodium Monomercaptoundecahydro-closododecaborate

Designated Indication:
For use in boron neutron capture therapy (BNCT) in the treatment of glioblastoma multiforme

Trade Name (if present):
Borocell

Date Designated 4/15/1992
Date Approved

Sponsor Contact Information
Neutron Technology Corp & Neutron R&D Partner
877 Main Street, Suite 402
Boise ID 83702

Generic Name:
Inosine pranobex

Designated Indication:
Treatment of subacute sclerosing panencephalitis.

Trade Name (if present):
Isoprinosine

Date Designated 9/20/1988
Date Approved

Sponsor Contact Information
Newport Pharmaceuticals
897 West Sixteenth Street
Newport Beach CA 92663

Generic Name:
Hypericin

Designated Indication:
Treatment of glioblastoma multiforme

Trade Name (if present):

Date Designated 8/3/2000
Date Approved

Sponsor Contact Information
Nexell Therapeutics
2751 Centerville Rd., Suite 210
Wilmington DE 19808

Generic Name:
T-cell depleted stem cell enriched cellular product from peripherial blood stem cells

Designated Indication:
Treatment of chronic granulomatous disease

Trade Name (if present):

Date Designated 11/1/2001
Date Approved

Sponsor Contact Information
Nexell Therapeutics Inc.
9 Parker
Irvine CA 92618-1605

Generic Name:
Hypericin

Designated Indication:
Treatment of cutaneous T-cell lymphoma.

Trade Name (if present):

Date Designated 2/7/2000
Date Approved

Sponsor Contact Information
Nexell Therapeutics, Inc.
2751 Centerville Rd., Suite 210
Wilmington DE 19808

Generic Name:
Daunorubicin citrate liposome injection

Designated Indication:
Treatment of patients with advanced HIV-associated Kaposi's sarcoma.

Trade Name (if present):
DaunoXome

Date Designated 5/14/1993
Date Approved 4/8/1996

Sponsor Contact Information
NeXstar Pharmaceuticals, Inc
650 Cliffside Drive
San Dimas CA 91773

Generic Name:
Autologous dendritic cells pulsed with autologous glioblastoma multiforme acid-eluted tumor antigens

Designated Indication:
Treatment of glioblastoma multiforme

Trade Name (if present):
DCVax-Brain

Date Designated 11/29/2002
Date Approved

Sponsor Contact Information
Northwest Biotherapeutics, Inc.
22322 20th Avenue SE
Suite 150
Bothell WA 98021

Generic Name:
Levodopa and carbidopa

Designated Indication:
Treatment of late stage Parkinson's disease

Trade Name (if present):
Duodopa

Date Designated 1/18/2000
Date Approved

Sponsor Contact Information
Nouvel Pharma, Inc.
11384 Strang Line Road
Lenexa KS 66215

Generic Name:
Calcitonin-human for injection

Designated Indication:
Treatment of symptomatic Paget's disease (osteitis deformans).

Trade Name (if present):
Cibacalcin

Date Designated 1/20/1987
Date Approved 10/31/1986

Sponsor Contact Information
Novartis Pharmaceutical Corporation
59 Route 10
East Hanover NJ 07936

Generic Name:
Clofazimine

Designated Indication:

Treatment of lepromatous leprosy, including dapsone-resistant lepromatous leprosy and lepromatous leprosy complicated by erythema nodosum leprosum.

Trade Name (if present):
Lamprene

Date Designated 6/11/1984
Date Approved 12/15/1986

Sponsor Contact Information

Novartis Pharmaceutical Corporation
59 Route 10
East Hanover NJ 07936

Generic Name:
imatinib mesylate

Designated Indication:
Treatment of gastrointestinal stromal tumors

Trade Name (if present):
Gleevec

Date Designated 11/1/2001
Date Approved 2/1/2002

Sponsor Contact Information

Novartis Pharmaceuticals Corp.
One Health Plaza
East Hanover NJ 07936-1080

Generic Name:
Zoledronate

Designated Indication:
Treatment of tumor induced hypercalcemia.

Trade Name (if present):
Zometa, Zabel

Date Designated 8/18/2000
Date Approved 8/20/2001

Sponsor Contact Information

Novartis Pharmaceuticals Corp.
59 Route 10
East Hanover NJ 07936-1080

Generic Name:
Deferasirox

Designated Indication:
Treatment of chronic iron overload in patients with transfusion-dependent anemias

Trade Name (if present):

Date Designated 11/21/2002
Date Approved

Sponsor Contact Information

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover NJ 07936-1080

Generic Name:
Imatinib

Designated Indication:
Treatment of chronic myelogenous leukemia

Trade Name (if present):
Gleevec

Date Designated 1/31/2001
Date Approved 5/10/2001

Sponsor Contact Information

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover NJ 07936-1080

Generic Name:
Octreotide

Designated Indication:
Treatment of diarrhea associated with vasoactive intestinal peptide tumors
(VIPoma)

Trade Name (if present):
Sandostatin LAR

Date Designated 8/24/1998
Date Approved 11/25/1998

Sponsor Contact Information
Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover NJ 07936-1080

Generic Name:
Octreotide

Designated Indication:
Treatment of acromegaly.

Trade Name (if present):
Sandostatin LAR

Date Designated 8/24/1998
Date Approved 11/25/1998

Sponsor Contact Information
Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover NJ 07936-1080

Generic Name:
Octreotide

Designated Indication:
Treatment of severe diarrhea and flushing associated with malignant carcinoid tumors.

Trade Name (if present):
Sandostatin LAR

Date Designated 8/24/1998
Date Approved 11/25/1998

Sponsor Contact Information
Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover NJ 07936-1080

Generic Name:
Basiliximab

Designated Indication:
Prophylaxis of solid organ rejection.

Trade Name (if present):
Simulect

Date Designated 12/12/1997
Date Approved 5/12/1998

Sponsor Contact Information
Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover NJ 07936-1080

Generic Name:
Sterile talc

Designated Indication:
Treatment of pneumothorax.

Trade Name (if present):
Steritalc

Date Designated 12/8/1997
Date Approved

Sponsor Contact Information
Novatech SA
Avenue du Vent des Dames - Z.I les Paluds
13685 Aubagne

FRANCE

Generic Name:
Sterile talc

Designated Indication:
Treatment of malignant pleural effusion.

Trade Name (if present):
Steritalc

Date Designated 12/8/1997
Date Approved

Sponsor Contact Information
Novatech SA
Avenue du Vent des Dames - Z1 les Paluds
13685 Aubagne

FRANCE

Generic Name:
NZ-1002

Designated Indication:
Enzyme replacement therapy in patients with all subtypes of
Mucopolysaccharidosis I

Trade Name (if present):

Date Designated 4/11/2001
Date Approved

Sponsor Contact Information
Novazyme Pharmaceuticals, Inc
800 Research Parkway
Suite 200
Oklahoma City OK 73104

Generic Name:
Recombinant human highly phosphorylated acid
alpha-glucosidase

Designated Indication:
For enzyme replacement therapy in patients with all subtypes of glycogen storage
disease type II (GSDII, Pompe Disease)

Trade Name (if present):
TBD

Date Designated 9/20/2000
Date Approved

Sponsor Contact Information
Novazyme Pharmaceuticals, Inc
800 Research Parkway
Suite 200
Oklahoma City OK 73104

Generic Name:
Somatropin (rDNA origin) injection

Designated Indication:
Treatment of growth failure in children due to inadequate growth hormone
secretion

Trade Name (if present):
Norditropin

Date Designated 7/10/1987
Date Approved

Sponsor Contact Information
Novo Nordisk Pharmaceuticals
100 Overlook Center
Suite 200
Princeton NJ 08540

Generic Name:
Coagulation factor VIIa (recombinant)

Designated Indication:
Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to
Factor VIII or Factor IX

Trade Name (if present):
NovoSeven

Date Designated 6/6/1988
Date Approved 3/25/1999

Sponsor Contact Information
Novo Nordisk Pharmaceuticals, Inc
100 Overlook Center
Suite 200
Princeton NJ 08540-7810

Generic Name:
9-nitro-20-(S)-camptothecin

Designated Indication:
Treatment of pediatric HIV infection/AIDS

Trade Name (if present):
Camvirex

Date Designated 5/15/2001
Date Approved

Sponsor Contact Information
NovoMed Pharmaceuticals, Inc
P O Box 900
Germantown MD 20875-0900

Generic Name:
5,5',5"-[Phosphinothioylidyne-tris(imino-2,1-ethanediyil)]tris[5-methylchelidoninium]trihydrodehexahydrochloride

Designated Indication:
Treatment of pancreatic cancer

Trade Name (if present):

Date Designated 8/20/2003
Date Approved

Sponsor Contact Information
Now Pharm AG
241, route d'Arlon
L-1150

LUXEMBOURG

Generic Name:
Recombinant glycine2-human glucagon-like peptide-2

Designated Indication:
Treatment of short bowel syndrome.

Trade Name (if present):

Date Designated 6/29/2000
Date Approved

Sponsor Contact Information
NPS Allelix Corp
6850 Goreway Dr.
Mississauga, Ontario L4V 1V7
CANADA

Generic Name:
Glutamine

Designated Indication:
For use with human growth hormone in the treatment of short bowel syndrome (nutrient malabsorption from the gastrointestinal tract resulting from an inadequate absorptive surface).

Trade Name (if present):

Date Designated 3/6/1995
Date Approved

Sponsor Contact Information
Nutritional Restart Pharmaceutical, L P.
4364 South Alston Avenue
Durham NC 27713

Generic Name:
Caffeine

Designated Indication:
Treatment of apnea of prematurity.

Trade Name (if present):
Cafcit

Date Designated 9/20/1988
Date Approved 9/21/1999

Sponsor Contact Information
O.P.R. Development, L P
1501 Wakarusa Drive
Lawrence KS 66047

Generic Name:
FIAU

Designated Indication:
Adjunctive treatment of chronic active hepatitis B

Trade Name (if present):

Date Designated 7/24/1992
Date Approved

Sponsor Contact Information
Oklassen Pharmaceuticals, Inc.
100 Pelican Way
San Rafael CA 94901

Generic Name:
Dexamethasone

Designated Indication:
For use in posterior segment drug delivery system in the treatment of idiopathic intermediate uveitis

Trade Name (if present):

Date Designated 9/11/1998
Date Approved

Sponsor Contact Information
Oculex Pharmaceuticals, Inc.
639 N Pastoria Avenue
Sunnyvale CA 94086-2917

Generic Name:
OM 401

Designated Indication:
Prophylactic treatment of sickle cell disease.

Trade Name (if present):

Drepanol

Date Designated 10/24/1991
Date Approved

Sponsor Contact Information
Omx International, Inc
6001 Savoy, Suite 110
Houston TX 77036

Generic Name:
polyinosinic-polycytidilic acid

Designated Indication:
Treatment of flavivirus infections including those due to West Nile, Japanese encephalitis, dengue, St Louis encephalitis, yellow fever, Murray valley, and Banzai viruses

Trade Name (if present):

Poly-ICLC

Date Designated 3/3/2003
Date Approved

Sponsor Contact Information
Oncovir
3203 Cleveland Ave , NW
Washington DC 20008-3450

Generic Name:
polyinosinic-polycytidilic acid

Designated Indication:
As an adjuvant to smallpox vaccination

Trade Name (if present):

Poly-ICLC

Date Designated 8/2/2002
Date Approved

Sponsor Contact Information
Oncovir
3203 Cleveland Ave., NW
Washington DC 20008-3450

Generic Name:
polyinosinic-polycytidilic acid (Poly-ICLC)

Designated Indication:
Treatment for orthopox virus infections

Trade Name (if present):
Hiltonol

Date Designated 11/19/2002
Date Approved

Sponsor Contact Information
Oncovir
3203 Cleveland Ave., NW
Washington DC 20008-3450

Generic Name:
Poly-ICLC

Designated Indication:
Treatment of primary brain tumors

Trade Name (if present):

Date Designated 3/17/1997
Date Approved

Sponsor Contact Information
Oncovir
3202 Cleveland Avenue N W
Washington DC 20008

Generic Name:
Calfactant

Designated Indication:
Acute respiratory distress syndrome (ARDS)

Trade Name (if present):
Infasurf

Date Designated 9/5/2000
Date Approved

Sponsor Contact Information
ONY, Inc.
Baird Research Park
1576 Sweet Home Road
Amherst NY 14228

Generic Name:
Surface active extract of saline lavage of bovine lungs

Designated Indication:
Treatment and prevention of respiratory failure due to pulmonary surfactant deficiency in preterm infants

Trade Name (if present):
Infasurf

Date Designated 6/7/1985
Date Approved

Sponsor Contact Information
ONY, Inc.
1576 Sweet Home Road
Amherst NY 14228

Generic Name:
Antivenom (crotalidae) purified (avian)

Designated Indication:
Treatment of envenomation by poisonous snakes belonging to the Crotalidae family

Trade Name (if present):

Date Designated 2/12/1991
Date Approved

Sponsor Contact Information
Ophidian Pharmaceuticals, Inc.
5445 East Cheryl Parkway
Madison WI 53711

Generic Name:
inolimomab

Designated Indication:
Treatment of graft versus host disease

Trade Name (if present):
Leukotac

Date Designated 10/23/2002
Date Approved

Sponsor Contact Information
Opi
6, Chemin de l'industrie
69570 DARDILLY - France

FRANCE

Generic Name:
Azathioprine

Designated Indication:
Treatment of oral manifestations of graft-versus-host disease

Trade Name (if present):
Imuran

Date Designated 9/14/1999
Date Approved

Sponsor Contact Information
Oral Solutions, Inc.
787 Seventh Ave., 48th Floor
New York NY 10019

Generic Name:
Toremifene

Designated Indication:
Treatment of desmoid tumors.

Trade Name (if present):

Date Designated 8/17/1993
Date Approved

Sponsor Contact Information
Orion Corporation
P.O. Box 65
02101 Espoo

FINLAND

Generic Name:
Toremifene

Designated Indication:
Hormonal therapy of metastatic carcinoma of the breast

Trade Name (if present):
Fareston

Date Designated 9/19/1991
Date Approved 5/29/1997

Sponsor Contact Information
Orion Corporation
P.O. Box 65
02101 ESPOO

FINLAND

Generic Name:
L-glutamine

Designated Indication:
Treatment of sickle cell disease

Trade Name (if present):

Date Designated 8/1/2001
Date Approved

Sponsor Contact Information
Orphan Drugs International, LLC (d.b.a. Hope Therapeutics)
PO Box 0401
Montrose CA 91021-0401

Generic Name:
octavalent Psuedomonas aeruginosa O-polysaccharide-toxin A conjugate

Designated Indication:
Prevention of Psuedomonas aeruginosa infections in patients with cystic fibrosis

Trade Name (if present):
Aerugen

Date Designated 5/16/2002
Date Approved

Sponsor Contact Information
Orphan Europe
Immeuble "Le Wilson"
70 avenue du General de Gaulle, 92046 Paris La Def

Generic Name:
Carbamylglutamic acid

Designated Indication:
Treatment of N-acetylglutamate synthetase deficiency.

Trade Name (if present):

Date Designated 1/20/1998
Date Approved

Sponsor Contact Information
Orphan Europe
Immeuble "Le Guillaumet"
60, avenue du General de Gaulle

FRANCE

Generic Name:
Heme arginate

Designated Indication:
Treatment of myelodysplastic syndromes

Trade Name (if present):

Normosang

Date Designated 3/1/1994
Date Approved

Sponsor Contact Information
Orphan Europe
Immeuble Le Guillaumet
70 avenue du General de Gaulle,
92056 Paris La Defense
FRANCE

Generic Name:
Heme arginate

Designated Indication:
Treatment of symptomatic stage of acute porphyria.

Trade Name (if present):

Normosang

Date Designated 3/10/1988
Date Approved

Sponsor Contact Information
Orphan Europe
Immeuble Le Guillaumet
92046 Paris La Defense

FRANCE

Generic Name:
Hydroxocobalamin

Designated Indication:
Treatment of acute cyanide poisoning

Trade Name (if present):

CYANOKIT

Date Designated 9/22/2000
Date Approved

Sponsor Contact Information
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 250
Minnetonka MN 55305

Generic Name:
Oxybate

Designated Indication:
Treatment of narcolepsy

Trade Name (if present):
Xyrem

Date Designated 11/7/1994
Date Approved 7/17/2002

Sponsor Contact Information
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 250
Minnetonka MN 55305

Generic Name:
Buffered intrathecal electrolyte/dextrose injection

Designated Indication:
For use as a diluent in the intrathecal administration of methotrexate and cytarabine for the prevention or treatment meningeal leukemia and lymphocytic lymphoma.

Trade Name (if present):
Elliott's B Solution

Date Designated 8/24/1994
Date Approved 9/27/1996

Sponsor Contact Information
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 475
Minnetonka MN 55305

Generic Name:
Busulfan

Designated Indication:
As preparative therapy in the treatment of malignancies with bone marrow transplantation.

Trade Name (if present):
Busulfex

Date Designated 7/28/1994
Date Approved 2/4/1999

Sponsor Contact Information
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 250
Minnetonka MN 55305

Generic Name:
Betaine

Designated Indication:
Treatment of homocystinuria.

Trade Name (if present):
Cystadane

Date Designated 5/16/1994
Date Approved 10/25/1996

Sponsor Contact Information
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 475
Minnetonka MN 55305

Generic Name:
Sacrosidase

Designated Indication:
Treatment of congenital sucrase-isomaltase deficiency.

Trade Name (if present):
Sucraid

Date Designated 12/10/1993
Date Approved 4/9/1998

Sponsor Contact Information
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 475
Minnetonka MN 55305

Generic Name:
Choline chloride

Designated Indication:

Treatment of choline deficiency, specifically the choline deficiency, hepatic steatosis, and cholestasis, associated with long-term parenteral nutrition

Trade Name (if present):
Intrachol

Date Designated 2/10/1994
Date Approved

Sponsor Contact Information
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 250
Minnetonka MN 55305

Generic Name:
Alpha-galactosidase A

Designated Indication:
Treatment of alpha-galactosidase A deficiency (Fabry's disease).

Trade Name (if present):
CC-galactosidase

Date Designated 6/17/1991
Date Approved

Sponsor Contact Information
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 475
Minnetonka MN 55305

Generic Name:
Fomepizole

Designated Indication:
Treatment of methanol or ethylene glycol poisoning.

Trade Name (if present):
Antizole

Date Designated 12/22/1988
Date Approved 12/8/2000

Sponsor Contact Information
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 250
Minnetonka MN 55305

Generic Name:
Fomepizole

Designated Indication:
Treatment of methanol or ethylene glycol poisoning

Trade Name (if present):
Antizole

Date Designated 12/22/1988
Date Approved 12/4/1997

Sponsor Contact Information
Orphan Medical, Inc.
13911 Ridgedale Drive
Suite 250
Minnetonka MN 55305

Generic Name:
Synthetic Human Parathyroid Hormone 1-34

Designated Indication:
Treatment of hypoparathyroidism

Trade Name (if present):

Date Designated 1/26/2001
Date Approved

Sponsor Contact Information
Orphan Pharmaceuticals, U S , Inc.
1101 Kermit Drive,
Suite 608
Nashville TN 37217

Generic Name:
L-cysteine

Designated Indication:
For the prevention and lessening of photosensitivity in erythropoietic protoporphyria.

Trade Name (if present):

Date Designated 5/16/1994
Date Approved

Sponsor Contact Information
Orphan Pharmaceuticals, U S A , Inc
1101 Kermit Dr
1101 Kermit Dr Suite 608
Nashville TN 37217

Generic Name:
Exisulind

Designated Indication:
For the suppression and control of colonic adenomatous polyps in the inherited disease adenomatous polyposis coli

Trade Name (if present):

Date Designated 2/14/1994
Date Approved

Sponsor Contact Information
OSI Pharmaceuticals, Inc
58 South Service Road
Suite 110
Melville NY 11747

Generic Name:
1,5-(Butylimino)-1,5 dideoxy,D-glucitol

Designated Indication:
Treatment of Fabry's disease.

Trade Name (if present):

Date Designated 5/12/1998
Date Approved

Sponsor Contact Information
Oxford GlycoSciences
10, The Quadrant
Abington Science Park
Abingdon, Oxfordshire OX14 3YS
UNITED KINGDOM

Generic Name:
Combretastatin A4 Phosphate

Designated Indication:
Treatment of anaplastic thyroid cancer, medullary thyroid cancer, and stage IV papillary or follicular thyroid cancer

Trade Name (if present):

Date Designated 7/23/2003
Date Approved

Sponsor Contact Information
OXiGENE, Inc
321 Arsenal Street
Watertown MA 02472

Generic Name:
Calcium gluconate gel 2.5%

Designated Indication:
Emergency topical treatment of hydrogen fluoride (hydrofluoric acid) burns

Trade Name (if present):

Date Designated 9/10/1990
Date Approved

Sponsor Contact Information
Paddock Laboratories, Inc.
3940 Quebec Avenue North
Minneapolis MN 55427

Generic Name:
Tiopronin

Designated Indication:
Prevention of cystine nephrolithiasis in patients with homozygous cystinuria

Trade Name (if present):
Thiola

Date Designated 1/17/1986
Date Approved 8/11/1988

Sponsor Contact Information
Pak, Charles Y C M D.

The University of Texas Health Scienc Center at Da
5323 Harry Hines Boulevard
Dallas TX 75235

Generic Name:
Dehydroepiandrosterone (DHEA)

Designated Indication:
Replacement therapy in individuals with adrenal insufficiency

Trade Name (if present):
Fideln

Date Designated 8/19/2003
Date Approved

Sponsor Contact Information
Paladin Labs, Inc
6111 Royalmount Avenue Suite 102
Montreal, Quebec , H4P 2T4
CANADA

Generic Name:
2-chloroethyl-3-sarcosinamide-1-nitrosourea

Designated Indication:
Treatment for malignant glioma

Trade Name (if present):
Sarmustine

Date Designated 11/15/2001
Date Approved

Sponsor Contact Information
Pangene Corporation
5500 Stewart Avenue
Fremont CA 94538

Generic Name:
Rifalazil

Designated Indication:
Treatment of pulmonary tuberculosis.

Trade Name (if present):

Date Designated 4/13/1999
Date Approved

Sponsor Contact Information
PathoGenesis Corporation
201 Elliott Avenue West
Suite 150
Seattle WA 98119

Generic Name:
Tobramycin for inhalation

Designated Indication:
Treatment of bronchopulmonary infections of Pseudomonas aeruginosa in cystic fibrosis patients.

Trade Name (if present):
TOBI

Date Designated 10/13/1994
Date Approved 12/22/1997

Sponsor Contact Information
Pathogenesis Corporation
201 Elliott Avenue West, Suite 150
Seattle WA 98119

Generic Name:
Thalidomide

Designated Indication:
Treatment and maintenance of rectional lepromatous leprosy

Trade Name (if present):

Date Designated 11/15/1988
Date Approved

Sponsor Contact Information
Pediatric Pharmaceuticals, Inc.
718 Bradford Avenue
Westfield NJ 07090

Generic Name:
Thalidomide

Designated Indication:
Treatment of graft versus host disease in patients receiving bone marrow transplantation

Trade Name (if present):

Date Designated 9/19/1988
Date Approved

Sponsor Contact Information
Pediatric Pharmaceuticals, Inc
718 Bradford Avenue
Westfield NJ 07090

Generic Name:
Thalidomide

Designated Indication:
Prevention of graft versus host disease in patients receiving bone marrow transplantation.

Trade Name (if present):

Date Designated 9/19/1988
Date Approved

Sponsor Contact Information
Pediatric Pharmaceuticals, Inc
718 Bradford Avenue
Westfield NJ 07090

Generic Name:
Apomorphine

Designated Indication:
Treatment of the on-off fluctuations associated with late-stage Parkinson's disease.

Trade Name (if present):

Date Designated 7/17/1995
Date Approved

Sponsor Contact Information
Pentech Pharmaceuticals, Inc
1110 Lake Cook Rd.
Suite 257
Buffalo Grove IL 60089

Generic Name:
Iodine I-131 radiolabeled chimeric MAb tumor necrosis treatment (TNT-1B)

Designated Indication:
Treatment of glioblastoma multiforme and anaplastic astrocytoma.

Trade Name (if present):
131I-chTNT-1

Date Designated 2/12/1999
Date Approved

Sponsor Contact Information
Peregrine Pharmaceuticals, Inc
14282 Franklin Ave.
Tustin CA 92780-7017

Generic Name:
Murine MAAb (Lym-1) and Iodine 131-I
radiolabeled murine MAAb (Lym-1) to human B-cell lymphoma

Trade Name (if present):
Oncolym

Date Designated 11/27/1998
Date Approved

Designated Indication:
Treatment of B-cell non-Hodgkin's lymphoma.

Generic Name:
Isobutyramide

Trade Name (if present):
Isobutyramide oral solution

Date Designated 12/18/1992
Date Approved

Sponsor Contact Information
Peregrine Pharmaceuticals, Inc
14272 Franklin Ave
Suite 100
Tustin CA 92780

Generic Name:
Arginine butyrate

Trade Name (if present):

Date Designated 4/7/1992
Date Approved

Designated Indication:
Treatment of beta-hemoglobinopathies and beta-thalassemia syndromes

Sponsor Contact Information
Perrine, Susan P , M D
Boston University
Cancer Research Center
Boston MA 02118

Trade Name (if present):

Date Designated 4/7/1992
Date Approved

Designated Indication:
Treatment of beta-hemoglobinopathies and beta-thalassemia

Trade Name (if present):
Cleocin

Date Designated 10/28/1988
Date Approved

Sponsor Contact Information
Pfizer Inc.
235 East 42nd Street
150-3-46
New York NY 10017

Generic Name:
Rifabutin

Trade Name (if present):

Date Designated 12/18/1989
Date Approved

Designated Indication:
Treatment of disseminated Mycobacterium avium complex disease.

Sponsor Contact Information
Pfizer, Inc.
235 East 42nd Street
New York NY 10017

Generic Name:
Dimethyl sulfoxide

Trade Name (if present):

Date Designated 11/22/1994
Date Approved

Designated Indication:

Treatment of increased intracranial pressure in patients with severe, closed-head injury, also known as traumatic brain coma, for whom no other effective treatment is available.

Sponsor Contact Information

Pharma 21
c/o Univ of Calif , San Diego
9500 Gilman Dr.
La Jolla CA 92093-0624

Generic Name:
Somatropin [rDNA]

Designated Indication:

Treatment of short stature in patients with Prader-Willi syndrome.

Trade Name (if present):
Genotropin

Sponsor Contact Information

Pharmacia & Upjohn
7000 Portage Rd
0633-298-113
Kalamazoo MI 49001-0199

Generic Name:
Somatropin

Designated Indication:

Treatment of adults with growth hormone deficiency

Trade Name (if present):
Genotropin

Sponsor Contact Information

Date Designated 9/6/1994
Date Approved 10/31/1997

Pharmacia & Upjohn

7000 Portage Road
Kalamazoo MI 49001-0199

Generic Name:
Dexrazoxane

Designated Indication:

For the prevention of cardiomyopathy associated with doxorubicin administration.

Trade Name (if present):
Zinecard

Sponsor Contact Information

Date Designated 12/17/1991
Date Approved 5/26/1995

Pharmacia & Upjohn

7000 Portage Road
Kalamazoo MI 49001-0199

Generic Name:
Exemestane

Designated Indication:

Treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.

Trade Name (if present):
Aromasin

Sponsor Contact Information

Date Designated 9/19/1991
Date Approved 10/21/1999

Pharmacia & Upjohn

7000 Portage Road
Mail Stop: 0636-298-113
Kalamazoo MI 49001-0199

Generic Name:
Idarubicin HCl for injection

Designated Indication:
Treatment of acute lymphoblastic leukemia in pediatric patients

Trade Name (if present):
Idamycin

Date Designated 2/12/1991
Date Approved

Sponsor Contact Information
Pharmacia & Upjohn
7000 Portage Road
Unit 0633-298-113
Kalamazoo MI 49001-0199

Generic Name:
Clindamycin

Designated Indication:
Treatment of Pneumocystis carinii pneumonia associated with AIDS patients

Trade Name (if present):
Cleocin

Date Designated 10/28/1988
Date Approved

Sponsor Contact Information
Pharmacia & Upjohn
7000 Portage Road
Unit 0633-298-113
Kalamazoo MI 49001-0199

Generic Name:
Antithrombin III (human)

Designated Indication:
For the treatment of patients with hereditary antithrombin III deficiency in connection with surgical or obstetrical procedures or when they suffer from thromboembolism.

Trade Name (if present):
ATnativ

Date Designated 2/8/1985
Date Approved 12/13/1989

Sponsor Contact Information
Pharmacia & Upjohn AB
Lindhagensgatan 133
SE-112 87

SWEDEN

Generic Name:
Epirubicin

Designated Indication:
Treatment of breast cancer

Trade Name (if present):
Ellence

Date Designated 9/14/1999
Date Approved 9/15/1999

Sponsor Contact Information
Pharmacia & Upjohn Company
0634-298-113
7000 Portage Rd
Kalamazoo MI 49001-0199

Generic Name:
somatropin [rDNA]

Designated Indication:
Treatment of growth failure in children who were born small for gestational age

Trade Name (if present):
Genotropin

Date Designated 12/27/2000
Date Approved 7/25/2001

Sponsor Contact Information
Pharmacia and Upjohn Company
7000 Portage Road
Kalamazoo MI 49001

Generic Name:
Superoxide dismutase (human)

Trade Name (if present):

Date Designated 3/6/1985
Date Approved

Designated Indication:

For protection of donor organ tissue from damage or injury mediated by oxygen-derived free radicals that are generated during the necessary periods of ischemia (hypoxia, anoxia), and especially reperfusion, associated with the operative procedure

Sponsor Contact Information

Pharmacia-Chiron Partnership
4560 Horton Street
Emeryville CA 94608

Generic Name:
motexafin gadolinium

Trade Name (if present):
Xcytrin

Date Designated 1/27/2003
Date Approved

Designated Indication:
For use in conjunction with whole brain radiation for the treatment of brain metastases arising from solid tumors

Sponsor Contact Information

Pharmacyclics, Inc.
999 East Arques Avenue
Sunnyvale CA 94085-4521

Generic Name:
Dehydroepiandrosterone sulfate sodium

Trade Name (if present):

Date Designated 1/28/1997
Date Approved

Designated Indication:
To accelerate the re-epithelialization of donor sites in those hospitalized burn patients who must undergo autologous skin grafting.

Sponsor Contact Information

Pharmadigm, Inc.
2401 Foothill Drive
Salt Lake City UT 84109-1405

Generic Name:
Dehydroepiandrosterone sulfate sodium

Trade Name (if present):

Date Designated 1/29/1997
Date Approved

Designated Indication:
Treatment of serious burns requiring hospitalization.

Sponsor Contact Information

Pharmadigm, Inc.
2401 Foothill Drive
Salt Lake City UT 84109-1405

Generic Name:
L-Baclofen

Trade Name (if present):

Date Designated 1/6/1998
Date Approved

Designated Indication:
Treatment of trigeminal neuralgia.

Sponsor Contact Information

Pharmascience Inc.
6111 Royalmount, #100
Montreal, Quebec H4P 2T4

CANADA

Generic Name:
L-Baclofen

Designated Indication:
Treatment of intractable spasticity in children with cerebral palsy.

Trade Name (if present):
Neuralgon

Sponsor Contact Information

Pharmascience Inc
6111 Royalmount, Suite 100
Montreal, Quebec H4P 2T4

CANADA

Generic Name:
L-baclofen

Designated Indication:
Treatment of intractable spasticity associated with spinal cord injury or multiple sclerosis

Trade Name (if present):
Neuralgon

Sponsor Contact Information

Pharmascience Inc.
6111 Royalmount, Suite 100
Montreal, Quebec H4P 2T4

CANADA

Generic Name:
Calcium acetate

Designated Indication:
Treatment of hyperphosphatemia in end stage renal disease.

Trade Name (if present):

Sponsor Contact Information

Pharmedic Company
28101 Ballard Road, Suite F
Lake Forest IL 60045

Generic Name:
Recombinant human C1-esterase inhibitor

Designated Indication:
Treatment of (acute attacks of) angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency

Trade Name (if present):

Sponsor Contact Information

Pharming N.V.
Cipalstreet 3
B-2440 Geel

BELGIUM

Generic Name:
Recombinant human C1-esterase inhibitor

Designated Indication:
Prophylactic treatment of angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.

Trade Name (if present):

Sponsor Contact Information

Pharming N V
Cipalstreet 3
B-2440 Geel

BELGIUM

Generic Name:
Human acid precursor alpha-glucosidase,
recombinant

Designated Indication:
Treatment of glycogen storage disease type II.

Trade Name (if present):

Date Designated 9/10/1996
Date Approved

Sponsor Contact Information
Pharming/Genzyme LLC
c/o Genzyme Corporation
1 Mountain Rd.
Framingham MA 01701-9322

Generic Name:
azacitidine

Designated Indication:
Treatment of myelodysplastic syndromes

Trade Name (if present):
Vidaza

Date Designated 12/3/2001
Date Approved

Sponsor Contact Information
Pharmion Corporation
4865 Riverbend Road
Boulder CO 80301

Generic Name:
(R)-N-[2-(6-Chloro-methoxy-1H-indol-3-yl)propyl]acetamide

Designated Indication:
Treatment of neuroleptic-induced tardive dyskinesia in schizophrenia patients

Trade Name (if present):

Date Designated 7/3/2003
Date Approved

Sponsor Contact Information
Phase 2 Discovery, Inc
3130 Highland Ave
Third Floor
Cincinnati OH 45219

Generic Name:
(R)-N-[2-(6-chloro-5-methoxy-1H-indol-3-yl)propyl]acetamide

Designated Indication:
Treatment of circadian rhythm sleep disorders in blind people with no light perception

Trade Name (if present):

Date Designated 10/3/2001
Date Approved

Sponsor Contact Information
Phase 2 Discovery, Inc.
3130 Highland Avenue, Third Floor
Cincinnati OH 45219-2374

Generic Name:
Pegylated arginine deiminase

Designated Indication:
Treatment of invasive malignant melanoma.

Trade Name (if present):
Melanocid

Date Designated 4/12/1999
Date Approved

Sponsor Contact Information
Phoenix Pharmacologics, Inc.
115 John Robert Thomas Dr
Exton PA 19341

Generic Name:
Polyethylene glycol-modified uricase

Designated Indication:
Treatment of tumor lysis syndrome in cancer patients undergoing chemotherapy.

Trade Name (if present):
Zurase

Date Designated 12/21/1998
Date Approved

Sponsor Contact Information
Phoenix Pharmacologies, Inc.
115 John Robert Thomas Dr
Exton PA 19341

Generic Name:
Pegylated arginine deiminase

Designated Indication:
Treatment of hepatocellular carcinoma

Trade Name (if present):
Hepacid

Date Designated 3/26/1999
Date Approved

Sponsor Contact Information
Phoenix Pharmacologies, Inc.
115 John Robert Thomas Dr.
Exton PA 19341

Generic Name:
Polyethylene glycol-modified uricase

Designated Indication:
Prophylaxis of hyperuricemia in cancer patients prone to develop tumor lysis syndrome during chemotherapy

Trade Name (if present):
Zurase

Date Designated 9/14/1999
Date Approved

Sponsor Contact Information
Phoenix Pharmacologies, Inc.
115 John Robert Thomas Dr
Exton PA 19341

Generic Name:
Botulinum toxin type A

Designated Indication:
Treatment of essential blepharospasm.

Trade Name (if present):
Dysport

Date Designated 3/23/1989
Date Approved

Sponsor Contact Information
Porton International, Inc.
1155 15th Street, N.W., #315
Washington DC 20005

Generic Name:
Erwinia L-asparaginase

Designated Indication:
Treatment of acute lymphocytic leukemia

Trade Name (if present):
Erwinase

Date Designated 7/30/1986
Date Approved

Sponsor Contact Information
Porton International, Inc.
7114 Springbrook Terrace, #200
Spotsylvania VA 22553

Generic Name:
Transgenic human alpha 1 antitrypsin

Designated Indication:
Treatment of emphysema secondary to alpha 1 antitrypsin deficiency.

Trade Name (if present):

Date Designated 5/19/1999
Date Approved

Sponsor Contact Information
PPL Therapeutics (Scotland) Limited
Roslin, Edinburgh
EH259PP Scotland

UNITED KINGDOM

Generic Name:
recombinant human alpha-1 antitrypsin

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):

Date Designated 3/6/1998
Date Approved

Sponsor Contact Information
PPL Therapeutics (Scotland) Limited
Roslin, Edinburgh
EH259PP Scotland

UNITED KINGDOM

Generic Name:
Tetrabenazine

Designated Indication:
Treatment of Huntington's disease.

Trade Name (if present):

Date Designated 12/11/1997
Date Approved

Sponsor Contact Information
Prestwick Pharmaceuticals, Inc.
1825 K Street NW
Suite 1475
Washington DC 20006

Generic Name:
Tetrabenazine

Designated Indication:
Treatment of moderate/severe tardive dyskinesia.

Trade Name (if present):

Date Designated 5/12/1998
Date Approved

Sponsor Contact Information
Prestwick Pharmaceuticals, Inc.
1825 K Street, NW
Suite 1475
Washington DC 20006

Generic Name:
tinidazole

Designated Indication:
Treatment of giardiasis

Trade Name (if present):

Date Designated 4/18/2002
Date Approved

Sponsor Contact Information
Presutti Laboratories, Inc
1607 N. Douglas Ave.
Arlington Heights IL 60004

Generic Name:
Tinidazole

Designated Indication:
For the treatment of amebiasis

Trade Name (if present):

Date Designated 8/20/2003
Date Approved

Sponsor Contact Information
Presutti Laboratories, Inc
1607 N. Douglas Avenue
Arlington Heights IL 60004

Generic Name:
digitoxin

Designated Indication:
Treatment of ovarian cancer

Trade Name (if present):

Date Designated 11/2/2001
Date Approved

Sponsor Contact Information
PrimeCyte, Inc.
130 Fifth Ave., N
Seattle WA 98109-4933

Generic Name:
digitoxin

Designated Indication:
Treatment of soft tissue sarcomas

Trade Name (if present):

Date Designated 10/18/2001
Date Approved

Sponsor Contact Information
PrimeCyte, Inc.
130 Fifth Ave., N.
Seattle WA 98109-4933

Generic Name:
Chlorhexidine gluconate mouthrinse

Designated Indication:
For use in the amelioration of oral mucositis associated with cytoreductive therapy used in conditioning patients for bone marrow transplantation therapy.

Trade Name (if present):

Peridex

Date Designated 8/18/1986
Date Approved

Sponsor Contact Information
Procter & Gamble Company
Sharon Wood Technical Center
11370 Reed Hartman Highway
Cincinnati OH 45241

Generic Name:
Omega-3 (n-3) polyunsaturated fatty acids

Designated Indication:
Treatment of IgA nephropathy.

Trade Name (if present):

Omacor

Date Designated 5/4/2000
Date Approved

Sponsor Contact Information
Pronova Biocare, AS
PO Box 420
1327 Lysaker

NORWAY

Generic Name:
DHA-paclitaxel

Designated Indication:
Treatment of metastatic malignant melanoma

Trade Name (if present):
Taxopremin

Sponsor Contact Information
Protarga, Inc.
2200 Renaissance Boulevard
Suite 450
King of Prussia PA 19406

Date Designated 10/10/2002
Date Approved

Generic Name:
DHA-paclitaxel

Designated Indication:
Treatment of adenocarcinoma of the stomach or lower esophagus

Trade Name (if present):
Taxopremin

Sponsor Contact Information
Protarga, Inc.
2200 Renaissance Boulevard
Suite 450
King of Prussia PA 19406

Date Designated 5/1/2003
Date Approved

Generic Name:
DHA-paclitaxel

Designated Indication:
Treatment of pancreatic cancer

Trade Name (if present):
Taxopremin

Sponsor Contact Information
Protarga, Inc.
2200 Renaissance Blvd
Suite 450
King of Prussia PA 19406

Date Designated 9/25/2001
Date Approved

Generic Name:
docosahexanoic acid-paclitaxel

Designated Indication:
Treatment of hormone-refractory prostate cancer

Trade Name (if present):
Taxopremin

Sponsor Contact Information
Protarga, Inc.
1100 East Hector Street
Suite 450
Conshohocken PA 19428-2377

Date Designated 3/5/2001
Date Approved

Generic Name:
lintuzumab

Designated Indication:
Treatment of acute myelogenous leukemia

Trade Name (if present):
Zamyl

Sponsor Contact Information
Protein Design Labs, Inc
34801 Campus Drive
Fremont CA 94555

Date Designated 9/9/2002
Date Approved

Generic Name:
Hu1D10, humanized monoclonal antibody

Designated Indication:
For use in the treatment of 1D10+ B cell non-Hodgkin's lymphoma

Trade Name (if present):
Remitogen

Sponsor Contact Information
Protein Design Labs, Inc
34801 Campus Drive
Fremont CA 94555

Date Designated 11/28/2001
Date Approved

Generic Name:
human gammaglobulin

Designated Indication:
Treatment for juvenile rheumatoid arthritis

Trade Name (if present):

Sponsor Contact Information
Protein Therapeutics, Inc
2761 N. Country Club Rd
Suite 202
Tucson AZ 85716

Date Designated 5/25/2001
Date Approved

Generic Name:
human gammaglobulin

Designated Indication:
Treatment of gastrointestinal disturbances (to include constipation, diarrhea, and abdominal pain) associated with regression-onset autism in pediatric patients.

Trade Name (if present):

Sponsor Contact Information
Protein Therapeutics, Inc
2761 N Country Club Rd.
Suite 202
Tucson AZ 85716

Date Designated 9/16/2002
Date Approved

Generic Name:
human gammaglobulin

Designated Indication:
Treatment of idiopathic inflammatory myopathies

Trade Name (if present):

Sponsor Contact Information
Protein Therapeutics, Inc.
2761 N Country Club Road
Suite 202
Tucson AZ 85716

Date Designated 11/14/2003
Date Approved

Generic Name:
Carboxypeptidase G2

Designated Indication:
Treatment of patients at risk of methotrexate toxicity

Trade Name (if present):

Sponsor Contact Information
Protherics, Inc
5214 Maryland Way, Suite 405
Brentwood TN 37027

Date Designated 8/19/2003
Date Approved

Generic Name:
Antivenin, crotalidae polyvalent immune Fab
(ovine)

Trade Name (if present):
CroFab

Date Designated 1/12/1994
Date Approved 10/2/2000

Designated Indication:
Treatment of envenomations inflicted by North American crotalid snakes.

Sponsor Contact Information
Protherics, Inc
1207 17th Ave. S , Suite 103
Nashville TN 37212

Generic Name:
Ganaxolone

Trade Name (if present):

Date Designated 5/25/1994
Date Approved

Designated Indication:
Treatment of infantile spasms.

Sponsor Contact Information
Purdue Pharma L.P.
One Stamford Forum
Stamford CT 06901-3431

Generic Name:
Porfimer sodium

Trade Name (if present):
Photofrin

Date Designated 11/15/1989
Date Approved

Designated Indication:
For the photodynamic therapy of patients with transitional cell carcinoma in situ of the urinary bladder

Sponsor Contact Information
QLT Phototherapeutics, Inc
Lederle Laboratories
401 North Middletown Road
Pearl River NY 10965

Generic Name:
Porfimer sodium

Trade Name (if present):
Photofrin

Date Designated 6/6/1989
Date Approved 12/27/1995

Designated Indication:
For the photodynamic therapy of patients with primary or recurrent obstructing (either partially or completely) esophageal carcinoma

Sponsor Contact Information
QLT Phototherapeutics, Inc
Lederle Laboratories
401 North Middletown Road
Pearl River NY 10965

Generic Name:
repository corticotropin or adrenocorticotropic hormone

Trade Name (if present):
H.P. Acthar Gel

Date Designated 5/21/2003
Date Approved

Designated Indication:
Treatment of infantile spasms

Sponsor Contact Information
Questcor Pharmaceuticals, Inc
3260 Whipple Road
Union City CA 94587-1217

Generic Name:
Sodium dichloroacetate

Designated Indication:
Treatment of severe head injury.

Trade Name (if present):
Ceresme

Date Designated 6/14/1999
Date Approved

Sponsor Contact Information
Questcor Pharmaceuticals, Inc.
26118 Research Road
Hayward CA 94545

Generic Name:
Fructose-1,6-diphosphate

Designated Indication:
Treatment of painful vaso-occlusive episodes associated with sickle cell disease

Trade Name (if present):
Codox

Date Designated 5/29/1998
Date Approved

Sponsor Contact Information
Questcor Pharmaceuticals, Inc.
3260 Whipple Road
Union City CA 94587-1217

Generic Name:
Sodium dichloroacetate

Designated Indication:
Treatment of congenital lactic acidosis

Trade Name (if present):

Date Designated 12/31/1997
Date Approved

Sponsor Contact Information
Questcor Pharmaceuticals, Inc.
3260 Whipple Rd
Union City CA 94587-1217

Generic Name:
Calcium carbonate

Designated Indication:
Treatment of hyperphosphatemia in patients with end stage renal disease.

Trade Name (if present):
R & D calcium carbonate/600

Date Designated 6/6/1990
Date Approved

Sponsor Contact Information
R & D Laboratories, Inc
4204 Glencoe Avenue
Marina Del Rey CA 90292

Generic Name:
Cladribine

Designated Indication:
Treatment of the chronic progressive form of multiple sclerosis.

Trade Name (if present):
Mylinax

Date Designated 4/19/1994
Date Approved

Sponsor Contact Information
R W Johnson Pharmaceutical Research Institute
Route 202
PO Box 300
Raritan NJ 08869-0602

Generic Name:
Topiramate

Designated Indication:
Treatment of Lennox-Gastaut syndrome.

Trade Name (if present):
Topamax

Sponsor Contact Information

R. W. Johnson Pharmaceutical Research Institute
Route 202, P O. Box 300
Raritan NJ 08869-0602

Date Designated 11/25/1992
Date Approved 8/28/2001

Generic Name:
Cladribine

Designated Indication:
Treatment of non-Hodgkin's lymphoma.

Trade Name (if present):
Leustatin Injection

Sponsor Contact Information

R. W. Johnson Pharmaceutical Research Institute
Route 202 South, P.O. Box 300
Raritan NJ 08869-0602

Date Designated 4/19/1993
Date Approved

Generic Name:
Cladribine

Designated Indication:
Treatment of chronic lymphocytic leukemia.

Trade Name (if present):
Leustatin Injection

Sponsor Contact Information

R. W. Johnson Pharmaceutical Research Institute
Route 202, P O. Box 300
Raritan NJ 08869-0602

Date Designated 12/31/1990
Date Approved

Generic Name:
Cladribine

Designated Indication:
Treatment of hairy cell leukemia.

Trade Name (if present):
Leustatin Injection

Sponsor Contact Information

R. W. Johnson Pharmaceutical Research Institute
Route 202, P.O. Box 300
Raritan NJ 08869

Date Designated 11/15/1990
Date Approved 2/26/1993

Generic Name:
Epoetin alpha

Designated Indication:
Treatment of HIV associated anemia related to HIV infection or HIV treatment

Trade Name (if present):
Procrit

Sponsor Contact Information

R. W. Johnson Pharmaceutical Research Institute
Route 202, P.O. Box 300
Raritan NJ 08869

Date Designated 3/7/1989
Date Approved

Generic Name:
Epoetin alpha

Designated Indication:
Treatment of anemia of prematurity in preterm infants.

Trade Name (if present):
Procrit

Sponsor Contact Information

R. W. Johnson Pharmaceutical Research Institute
Route 202, P.O. Box 300
Raritan NJ 08869-0602

Date Designated 7/21/1988
Date Approved

Generic Name:
Epoetin alpha

Designated Indication:
Treatment of anemia associated with end stage renal disease

Trade Name (if present):
Procrit

Sponsor Contact Information

R. W. Johnson Pharmaceutical Research Institute
Route 202 South
P.O. Box 300
Raritan NJ 08869

Date Designated 8/27/1987
Date Approved

Generic Name:
Latrodectus immune F(ab)2

Designated Indication:
Treatment of black widow spider envenomations

Trade Name (if present):
Aracmyn

Sponsor Contact Information

Rare Disease Therapeutics, Inc.
1101 Kermit Drive, Suite 608
Nashville TN 37217

Date Designated 6/18/2001
Date Approved

Generic Name:
Buprenorphine hydrochloride

Designated Indication:
Treatment of opiate addiction in opiate users.

Trade Name (if present):
Subutex

Sponsor Contact Information

Date Designated 6/15/1994
Date Approved 10/8/2002

Reckitt Benckiser Pharmaceuticals, Inc.
1901 Huguenot Road
Richmond VA 23235

Generic Name:
Buprenorphine in combination with naloxone

Designated Indication:
Treatment of opiate addiction in opiate users

Trade Name (if present):
Suboxone

Sponsor Contact Information

Date Designated 10/27/1994
Date Approved 10/8/2002

Reckitt Benckiser Pharmaceuticals, Inc.
1901 Huguenot Road
Richmond VA 23235

Generic Name:
Ciliary neurotrophic factor

Designated Indication:
Treatment of amyotrophic lateral sclerosis

Trade Name (if present):

Date Designated 1/30/1992
Date Approved

Sponsor Contact Information
Regeneron Pharmaceuticals Inc
777 Old Saw Mill River Road
Tarrytown NY 10591

Generic Name:
Gossypol

Designated Indication:
Treatment of cancer of the adrenal cortex

Trade Name (if present):

Date Designated 10/22/1990
Date Approved

Sponsor Contact Information
Reidenberg, Marcus M. M.D.
The New York Hospital - Cornell Medical Center
525 East 68th Street, Box 70
New York NY 10021

Generic Name:
2',3',5'-tri-o-acetyluridine

Designated Indication:
Treatment of mitochondrial disease

Trade Name (if present):

Date Designated 1/13/2003
Date Approved

Sponsor Contact Information
Repligen Corporation
41 Seyon Street
Building 1, Suite 100
Waltham MA 02453

Generic Name:
Omega-3 (n-3) polyunsaturated fatty acid with
all double bonds in the cis configuration

Designated Indication:
Prevention of organ graft rejection.

Trade Name (if present):

Date Designated 11/22/1995
Date Approved

Sponsor Contact Information
Research Triangle Pharmaceuticals
4364 South Alston Avenue
Durham NC 27713

Generic Name:
Vasoactive intestinal polypeptide

Designated Indication:
Treatment of acute esophageal food impaction.

Trade Name (if present):

Date Designated 6/23/1993
Date Approved

Sponsor Contact Information
Research Triangle Pharmaceuticals
200 Westpark Corporate Center
4364 South Alston Avenue
Durham NC 27713-2280

Generic Name:
Rho (D) immune globulin intravenous (human)

Designated Indication:
Treatment of immune thrombocytopenic purpura

Trade Name (if present):
WinRhe SD

Sponsor Contact Information
Rh Pharmaceuticals, Inc
104 Chancellor Matheson Road
Winnipeg, Manitoba R3T 2N2
CANADA

Date Designated 11/9/1993
Date Approved 3/24/1995

Generic Name:
Riluzole

Designated Indication:
Treatment of Huntington's disease.

Trade Name (if present):
Rilutek

Sponsor Contact Information
Rhone-Poulenc Rorer Pharmaceuticals, Inc
500 Arcola Road
PO Box 5096
Collegeville PA 19426-0800

Date Designated 10/15/1996
Date Approved

Generic Name:
Riluzole

Designated Indication:
Treatment of amyotrophic lateral sclerosis.

Trade Name (if present):
Rilutek

Sponsor Contact Information
Rhone-Poulenc Rorer Pharmaceuticals, Inc
500 Arcola Road, P O. Box 1200
Collegeville PA 19426

Date Designated 3/16/1993
Date Approved 12/12/1995

Generic Name:
Teriparatide

Designated Indication:
Diagnostic agent to assist in establishing the diagnosis in patients presenting with clinical and laboratory evidence of hypocalcemia due to either hypoparathyroidism or pseudohypoparathyroidism.

Trade Name (if present):
Parathar

Sponsor Contact Information
Rhone-Poulenc Rorer Pharmaceuticals, Inc
500 Arcola Road
Collegeville PA 19426

Date Designated 1/9/1987
Date Approved 12/23/1987

Generic Name:
Tiazofurin (2-Beta-D-ribofuranosyl-4-thiazolecarboxamide)

Designated Indication:
Chronic myelogenous leukemia (CML)

Trade Name (if present):

Sponsor Contact Information
Ribapharm
3300 Hyland Avenue
Costa Mesa CA 92626

Date Designated 12/27/2000
Date Approved

Generic Name:
Melanoma vaccine

Designated Indication:
Treatment of stage III - IV melanoma.

Trade Name (if present):
Melaccine

Date Designated 12/20/1989
Date Approved

Sponsor Contact Information
Ribi ImmunoChem Research, Inc
533 Old Corvallis Road
Hamilton MT 59840

Generic Name:
Short chain fatty acid solution

Designated Indication:
Treatment of the active phase of ulcerative colitis with involvement restricted to the left side of the colon

Trade Name (if present):
Colomed

Date Designated 5/29/1990
Date Approved

Sponsor Contact Information
Richard I. Breuer
1000 Central Street, Suite 615
Evanston IL 60201

Generic Name:
Short chain fatty acid enema

Designated Indication:
Treatment of chronic radiation proctitis.

Trade Name (if present):
Colomed

Date Designated 8/19/1997
Date Approved

Sponsor Contact Information
Richard I. Breuer, M D
1000 Central Street, Suite 615
Evanston IL 60201

Generic Name:
Alendronate disodium

Designated Indication:
Treatment of the bone manifestations of Gaucher disease

Trade Name (if present):
Fosamax

Date Designated 2/13/2001
Date Approved

Sponsor Contact Information
Richard J. Wenstrup, M D
Division of Human Genetics
Children's Hospital Research Foundation
Cincinnati OH 45229-3039

Generic Name:
Anagrelide

Designated Indication:
Treatment of essential thrombocythemia.

Trade Name (if present):
Agylin

Date Designated 1/27/1988
Date Approved 3/14/1997

Sponsor Contact Information
Roberts Pharmaceutical Corp
Meridian Center III
6 Industrial Way West
Eatontown NJ 07724

Generic Name:
Deslorelin

Designated Indication:

Trade Name (if present):
Somagard

Date Designated 11/5/1987
Date Approved

Sponsor Contact Information
Roberts Pharmaceutical Corp
Meridian Center II
Four Industrial Way West
Eatontown NJ 07724-2274

Generic Name:
Histrelin acetate

Designated Indication:
Treatment of central precocious puberty.

Trade Name (if present):
Supprelin Injection

Date Designated 8/10/1988
Date Approved 12/24/1991

Sponsor Contact Information
Roberts Pharmaceutical Corp
Meridian Center III
6 Industrial Way West
Eatontown NJ 07724

Generic Name:
Anagrelide

Designated Indication:
Treatment of thrombocytosis in chronic myelogenous leukemia.

Trade Name (if present):
Agrylm

Date Designated 7/14/1986
Date Approved

Sponsor Contact Information
Roberts Pharmaceutical Corp
Meridian Center II
4 Industrial Way West
Eatontown NJ 07724-2274

Generic Name:
Anagrelide

Designated Indication:
Treatment of polycythemia vera.

Trade Name (if present):
Agrylm

Date Designated 6/11/1985
Date Approved

Sponsor Contact Information
Roberts Pharmaceutical Corp
Meridian Center II
4 Industrial Way West
Eatontown NJ 07724-2274

Generic Name:
nitazoxanide

Designated Indication:
Treatment of intestinal giardiasis

Trade Name (if present):
Alinia

Date Designated 2/14/2002
Date Approved 11/22/2002

Sponsor Contact Information
Romark Laboratories, L.C.
6200 Courtney Campbell Causeway
Suite 880
Tampa FL 33607

Generic Name:
nitazoxanide

Designated Indication:
Treatment for intestinal amebiasis

Trade Name (if present):
Cryptaz

Date Designated 10/23/2001
Date Approved

Sponsor Contact Information
Romark Laboratories, L C.
6200 Courtney Campbell Causeway
Suite 880
Tampa FL 33607

Generic Name:
Nitazoxanide

Designated Indication:
Treatment of cryptosporidiosis

Trade Name (if present):
Almia

Date Designated 12/12/1996
Date Approved 11/22/2002

Sponsor Contact Information
Romark Laboratories, L C.
6200 Courtney Campbell Causeway
Suite 880
Tampa FL 33607

Generic Name:
Beractant

Designated Indication:
Treatment of full-term newborn infants with respiratory failure caused by meconium aspiration syndrome, persistent pulmonary hypertension of the newborn, or pneumonia and sepsis

Trade Name (if present):
Survanta Intratracheal Suspension

Date Designated 12/20/1993
Date Approved

Sponsor Contact Information
Ross Laboratories
625 Cleveland Avenue
Columbus OH 43215

Generic Name:
Beractant

Designated Indication:
Prevention of neonatal respiratory distress syndrome.

Trade Name (if present):
Survanta intratracheal suspension

Date Designated 2/5/1986
Date Approved 7/1/1991

Sponsor Contact Information
Ross Laboratories
625 Cleveland Avenue
Columbus OH 43215

Generic Name:
Beractant

Designated Indication:
Treatment of neonatal respiratory distress syndrome

Trade Name (if present):
Survanta intratracheal suspension

Date Designated 2/5/1986
Date Approved 7/1/1991

Sponsor Contact Information
Ross Laboratories
625 Cleveland Avenue
Columbus OH 43215

Generic Name:
Clonidine

Trade Name (if present):
Duraclon

Date Designated 1/24/1989
Date Approved 10/2/1996

Designated Indication:

For continuous epidural administration as adjunctive therapy with intraspinal opiates for the treatment of pain in cancer patients tolerant to, or unresponsive to, intraspinal opiates.

Sponsor Contact Information
Roxane Laboratories, Inc
PO Box 16532
Columbus OH 43216-6532

Generic Name:
Cyclosporine in combination with omega-3 polyunsaturated fatty acids

Trade Name (if present):

Date Designated 12/6/2000
Date Approved

Designated Indication:
Prevention of solid organ graft rejection

Sponsor Contact Information
RTP Pharma Corporation
200 Westpark Corporate Center
4364 South Alston Avenue
Durham NC 27713-2280

Generic Name:
phenylephrine

Trade Name (if present):

Date Designated 2/14/2002
Date Approved

Designated Indication:
Treatment of ileal pouch anal anastomosis related fecal incontinence

Sponsor Contact Information
S.L.A. Pharma
Unit 3, Hill Farm Industrial Estate
Leavesden, Watford WD25 7SA
UNITED KINGDOM

Generic Name:
Melatonin

Trade Name (if present):

Date Designated 11/15/1993
Date Approved

Designated Indication:
Treatment of circadian rhythm sleep disorders in blind people with no light perception

Sponsor Contact Information
Sack, Robert, M.D.
Oregon Health Sciences University
3181 S W. Sam Jackson Park Road
Portland OR 97201

Generic Name:
Rifaximin

Trade Name (if present):
Normix

Date Designated 2/10/1998
Date Approved

Designated Indication:
Treatment of hepatic encephalopathy

Sponsor Contact Information
Salix Pharmaceuticals, Inc
3600 W. Bayshore Road, Suite 205
Palo Alto CA 94303

Generic Name:
Pergolide

Designated Indication:
Treatment of Tourette's syndrome.

Trade Name (if present):
Permax

Date Designated 11/20/1997
Date Approved

Sponsor Contact Information
Sallee, Floyd R M D , Ph.D
Cincinnati Children's Hospital Medical Center
3333 Burnet Ave
Cincinnati OH 45229-3039

Generic Name:
R-etodolac

Designated Indication:
The treatment of chronic lymphocytic leukemia

Trade Name (if present):

Date Designated 12/9/2002
Date Approved

Sponsor Contact Information
Salmedix, Inc.
4330 La Jolla Village Drive
Suite 250
San Diego CA 92122

Generic Name:
Vasoactive intestinal peptide

Designated Indication:
Treatment of Acute Respiratory Distress Syndrome

Trade Name (if present):

Date Designated 3/9/2001
Date Approved

Sponsor Contact Information
Sami I Said, M D
State University of New York at Stony Brook
Healt Health Sciences Center T17, 040
Stony Brook NY 11794-8172

Generic Name:
Primaquine phosphate

Designated Indication:
For use in combination with clindamycin hydrochloride in the treatment of Pneumocystis carinii pneumonia associated with AIDS

Trade Name (if present):

Date Designated 7/23/1993
Date Approved

Sponsor Contact Information
Sanofi Winthrop, Inc.
90 Park Avenue
New York NY 10016

Generic Name:
Succimer

Designated Indication:
Prevention of cystine kidney stone formation in patients with homozygous cystinuria who are prone to stone development.

Trade Name (if present):
Chemet

Date Designated 11/5/1990
Date Approved

Sponsor Contact Information
Sanofi Winthrop, Inc.
90 Park Avenue
New York NY 10016-1389

Generic Name:
Succimer

Designated Indication:
Treatment of mercury intoxication

Trade Name (if present):
Chemet

Date Designated 3/22/1991
Date Approved

Sponsor Contact Information
Sanofi Winthrop, Inc
90 Park Avenue
New York NY 10016-1389

Generic Name:
tirapazamine

Designated Indication:
For the treatment of head and neck cancer

Trade Name (if present):

Date Designated 10/23/2002
Date Approved

Sponsor Contact Information
Sanofi-Synthelabo Research
9 Great Valley Parkway
Malvern PA 19355

Generic Name:
rasburicase

Designated Indication:
Treatment of malignancy-associated or chemotherapy-induced hyperuricemia

Trade Name (if present):
Elitek

Date Designated 10/11/2000
Date Approved 7/12/2002

Sponsor Contact Information
Sanofi-Synthelabo Research
9 Great Valley Parkway
Malvern PA 19355

Generic Name:
Recombinant urate oxidase

Designated Indication:
Prophylaxis of chemotherapy-induced hyperuricemia

Trade Name (if present):

Date Designated 10/11/2000
Date Approved

Sponsor Contact Information
Sanofi-Synthelabo Research
9 Great Valley Parkway
Malvern PA 19355

Generic Name:
ribavirin

Designated Indication:
Treatment of chronic hepatitis C in pediatric patients

Trade Name (if present):
REBETOL

Date Designated 4/4/2003
Date Approved 7/29/2003

Sponsor Contact Information
Schering Corporation
2000 Galloping Hill Road
Kenilworth NJ 07033

Generic Name:
SCH 58500

Designated Indication:
Treatment of primary ovarian cancer

Trade Name (if present):

Date Designated 4/12/1999
Date Approved

Sponsor Contact Information
Schering Corporation
2000 Galloping Hill Rd.
Kenilworth NJ 07033

Generic Name:
Interferon alfa-2b (recombinant)

Designated Indication:
Treatment of AIDS-related Kaposi's sarcoma

Trade Name (if present):
Intron A

Date Designated 6/24/1987
Date Approved 11/21/1988

Sponsor Contact Information
Schering Corporation
2000 Galloping Hill Road
Kenilworth NJ 07033

Generic Name:
Temozolomide

Designated Indication:
Treatment of advanced metastatic melanoma.

Trade Name (if present):
Temodal

Date Designated 10/14/1998
Date Approved

Sponsor Contact Information
Schering-Plough Research Institute
2000 Galloping Hill Rd.
Kenilworth NJ 07033

Generic Name:
Temozolomide

Designated Indication:
Treatment of recurrent malignant glioma.

Trade Name (if present):
Temodar

Date Designated 10/5/1998
Date Approved 8/11/1999

Sponsor Contact Information
Schering-Plough Research Institute
2000 Galloping Hill Rd.
Kenilworth NJ 07033

Generic Name:
Midodrine HCl

Designated Indication:
Treatment of patients with symptomatic orthostatic hypotension

Trade Name (if present):
Amatine

Date Designated 12/5/1996
Date Approved 9/6/1996

Sponsor Contact Information
Schier Ridgewood FKA (Roberts Pharmaceutical Corp)
Meridian Center III
6 Industrial Way West
Eatontown NJ 07724

Generic Name:
Thymalfasin

Designated Indication:
Treatment of hepatocellular carcinoma.

Trade Name (if present):
Zadaxin

Sponsor Contact Information
SciClone Pharmaceuticals, Inc.
901 Mariner's Blvd., Suite 205
San Mateo CA 94404-1593

Date Designated 3/6/2000
Date Approved

Generic Name:
Thymalfasin

Designated Indication:
Treatment of DiGeorge anomaly with immune defects

Trade Name (if present):
Zadaxin

Sponsor Contact Information
SciClone Pharmaceuticals, Inc
901 Mariner's Island Blvd.
San Mateo CA 94404-1593

Date Designated 1/8/1998
Date Approved

Generic Name:
8 Cyclopentyl 1,3-dipropylxanthine

Designated Indication:
Treatment of cystic fibrosis.

Trade Name (if present):

Sponsor Contact Information
SciClone Pharmaceuticals, Inc
901 Mariner's Island Boulevard
San Mateo CA 94404-1593

Date Designated 3/24/1997
Date Approved

Generic Name:
Thymalfasin

Designated Indication:
Treatment of chronic active hepatitis B.

Trade Name (if present):
Zadaxin

Sponsor Contact Information
SciClone Pharmaceuticals, Inc
901 Mariner's Island Blvd
San Mateo CA 94404-1593

Date Designated 5/3/1991
Date Approved

Generic Name:
Temoporfin

Designated Indication:
Palliative treatment of recurrent, refractory or second primary squamous cell carcinomas of the head and neck in patients considered to be incurable with surgery or radiotherapy.

Trade Name (if present):
Foscan

Sponsor Contact Information
Scotia Pharmaceuticals Ltd.
Scotia House, Castle Business Park
Stirling, Scotland FK9 4TZ
UNITED KINGDOM

Date Designated 10/28/1999
Date Approved

Generic Name:
SGN-30 (anti-CD30 mAb)

Designated Indication:
Treatment of Hodgkin's disease

Trade Name (if present):

Date Designated 7/18/2003
Date Approved

Sponsor Contact Information
Seattle Genetics, Inc
21823 30th Drive, Southeast
Bothell WA 98021

Generic Name:
diferuloylmethane

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):

Date Designated 6/13/2003
Date Approved

Sponsor Contact Information
Seer Pharmaceuticals, LLC
P. O Box 138
Southport CT 06890

Generic Name:
Pegvisomant

Designated Indication:
Treatment of acromegaly.

Trade Name (if present):
Somavert

Date Designated 6/24/1997
Date Approved 3/25/2003

Sponsor Contact Information
Sensus Corporation
Suite 430,
98 San Jacinto Boulevard
Austin TX 78701

Generic Name:
Mitoxantrone

Designated Indication:
Treatment of hormone refractory prostate cancer.

Trade Name (if present):
Novantrone

Date Designated 8/21/1996
Date Approved 11/13/1996

Sponsor Contact Information
Serono
One Technology Place
Rockland MA 02370

Generic Name:
Follitropin alfa, recombinant

Trade Name (if present):

Gonal-F

Date Designated 12/21/1998
Date Approved 5/24/2000

Designated Indication:
For the initiation and re-initiation of spermatogenesis in adult males with reproductive failure due to hypothalamic or pituitary dysfunction, hypogonadotropic hypogonadism. AMENDED indication 6/27/00. For the induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure

Sponsor Contact Information
Serono Laboratories, Inc.
100 Longwater Circle
Norwell MA 02061

Generic Name:
Urofollitropin

Trade Name (if present):
Fertmex

Date Designated 12/5/1997
Date Approved

Designated Indication:

For the initiation and re-initiation of spermatogenesis in adult males with reproductive failure due to hypothalamic or pituitary dysfunction, hypogonadotropic hypogonadism.

Sponsor Contact Information

Serono Laboratones, Inc
100 Longwater Circle
Norwell MA 02061

Generic Name:
Interferon beta-1a

Trade Name (if present):
Rebif

Date Designated 3/11/1996
Date Approved

Designated Indication:
Treatment of patients with secondary progressive multiple sclerosis.

Sponsor Contact Information

Serono Laboratones, Inc.
100 Longwater Circle
Norwell MA 02061

Generic Name:
Somatropin (r-DNA) for injection

Trade Name (if present):
Serostim

Date Designated 3/26/1996
Date Approved

Designated Indication:
Treatment of children with AIDS-associated failure-to-thrive including AIDS-associated wasting

Sponsor Contact Information

Serono Laboratories, Inc.
One Technology Place
Rockland MA 02370

Generic Name:
Somatropin (r-DNA)

Trade Name (if present):
Serostim

Date Designated 3/6/1995
Date Approved 12/1/2003

Designated Indication:
For use alone or in combination with glutamine in the treatment of short bowel syndrome.

Sponsor Contact Information

Serono Laboratories, Inc.
One Technology Place
Roackland MA 02370

Generic Name:
Recombinant human luteinizing hormone

Trade Name (if present):
LHadi

Date Designated 10/7/1994
Date Approved

Designated Indication:
For use in association with recombinant human follicle stimulating hormone for the treatment of women with chronic anovulation due to hypogonadotropic hypogonadism.

Sponsor Contact Information

Serono Laboratories, Inc.
100 Longwater Circle
Norwell MA 02061

Generic Name:
Tumor necrosis factor-binding protein II

Designated Indication:
Treatment of symptomatic patients with the AIDS including all patients with CD4 T-cell counts less than 200 cells per mm³.

Trade Name (if present):

Date Designated 1/6/1993
Date Approved

Sponsor Contact Information
Serono Laboratories, Inc
100 Longwater Circle
Norwell MA 02061

Generic Name:
Interferon beta-1a (recombinant)

Designated Indication:
Treatment of symptomatic patients with AIDS including all patients with CD4 T-cell counts less than 200 cells per mm³.

Trade Name (if present):
Rebif

Date Designated 12/2/1992
Date Approved

Sponsor Contact Information
Serono Laboratories, Inc
100 Longwater Circle
Norwell MA 02061

Generic Name:
Tumor necrosis factor-binding protein I

Designated Indication:
Treatment of symptomatic patients with AIDS including all patients with CD4 counts less than 200 cells per mm³.

Trade Name (if present):

Date Designated 1/6/1993
Date Approved

Sponsor Contact Information
Serono Laboratories, Inc
100 Longwater Circle
Norwell MA 02061

Generic Name:
Sermorelin acetate

Designated Indication:
Treatment of AIDS-associated catabolism/weight loss

Trade Name (if present):
Geref

Date Designated 12/5/1991
Date Approved

Sponsor Contact Information
Serono Laboratories, Inc.
One Technology Place
Rockland MA 02370

Generic Name:
Somatropin for injection

Designated Indication:
Treatment of AIDS-associated catabolism/weight loss.

Trade Name (if present):
Serostim

Date Designated 11/15/1991
Date Approved 8/23/1996

Sponsor Contact Information
Serono Laboratories, Inc.
100 Longwater Circle
Norwell MA 02061

Generic Name:
Sermorelin acetate

Trade Name (if present):

Geref

Date Designated 2/13/1990

Date Approved

Designated Indication:

Adjunct to gonadotropin therapy in the induction of ovulation in women with anovulatory or oligo-ovulatory infertility who fail to ovulate in response to adequate treatment with clomiphene citrate alone and gonadotropin therapy alone

Trade Name (if present):

Geref

Date Designated 2/13/1990

Date Approved

Sponsor Contact Information

Serono Laboratories, Inc
One Technology Place
Rockland MA 02370

Generic Name:
Somatropin (rDNA)

Trade Name (if present):

Saizen

Date Designated 5/3/1989

Date Approved

Designated Indication:

For the enhancement of nitrogen retention in hospitalized patients suffering from severe burns

Trade Name (if present):

Saizen

Date Designated 5/3/1989

Date Approved

Sponsor Contact Information

Serono Laboratories, Inc
One Technology Place
Rockland MA 02370

Generic Name:
Sermorelin acetate

Trade Name (if present):

Geref

Date Designated 9/14/1988

Date Approved 9/26/1997

Designated Indication:

Treatment of idiopathic or organic growth hormone deficiency in children with growth failure

Trade Name (if present):

Geref

Date Designated 9/14/1988

Date Approved 9/26/1997

Sponsor Contact Information

Serono Laboratories, Inc.
100 Longwater Circle
Norwell MA 02061

Generic Name:
Somatropin (rDNA origin)

Trade Name (if present):

Saizen

Date Designated 3/6/1987

Date Approved

Designated Indication:

Treatment of idiopathic or organic growth hormone deficiency in children with growth failure.

Trade Name (if present):

Saizen

Date Designated 3/6/1987

Date Approved

Sponsor Contact Information

Serono Laboratories, Inc.
100 Longwater Circle
Norwell MA 02061

Generic Name:
Urofollitropin

Trade Name (if present):

Metrodin

Date Designated 11/25/1987

Date Approved 9/18/1986

Designated Indication:

For induction of ovulation in patients with polycystic ovarian disease who have an elevated LH/FSH ratio and who have failed to respond to adequate clomiphene citrate therapy.

Sponsor Contact Information

Serono Laboratories, Inc.
100 Longwater Circle
Norwell MA 02061

Generic Name:
Butyrylcholinesterase

Designated Indication:
Treatment of post-surgical apnea

Trade Name (if present):

Date Designated 9/30/1992
Date Approved

Sponsor Contact Information
Shire Laboratories Inc
1550 East Gude Drive
Rockville MD 20850

Generic Name:
Butyrylcholinesterase

Designated Indication:
For the reduction and clearance of toxic blood levels of cocaine encountered during a drug overdose.

Trade Name (if present):

Date Designated 3/25/1992
Date Approved

Sponsor Contact Information
Shire Laboratories Inc
1550 East Gude Drive
Rockville MD 20850

Generic Name:
Cysteamine hydrochloride

Designated Indication:
Treatment of corneal cystine crystal accumulation in cystinosis patients

Trade Name (if present):

Date Designated 8/19/1997
Date Approved

Sponsor Contact Information
Sigma-Tau Pharmaceuticals, Inc.
800 South Frederick Avenue
Gaithersburg MD 20877

Generic Name:
Levocarnitine

Designated Indication:
Treatment of zidovudine-induced mitochondrial myopathy

Trade Name (if present):
Carnitor

Date Designated 4/7/1997
Date Approved

Sponsor Contact Information
Sigma-Tau Pharmaceuticals, Inc
800 S Frederick Avenue, Suite 300
Gaithersburg MD 20877

Generic Name:
Levocarnitine

Designated Indication:
Treatment of pediatric cardiomyopathy.

Trade Name (if present):
Carnitor

Date Designated 11/22/1993
Date Approved

Sponsor Contact Information
Sigma-Tau Pharmaceuticals, Inc
800 South Frederick Avenue
Gaithersburg MD 20877

Generic Name:
Levcarnitine

Designated Indication:
For the prevention of secondary carnitine deficiency in valproic acid toxicity

Trade Name (if present):
Carnitor

Date Designated 11/15/1989
Date Approved

Sponsor Contact Information
Sigma-Tau Pharmaceuticals, Inc
800 South Frederick Avenue
Gaithersburg MD 20877

Generic Name:
Levcarnitine

Designated Indication:
For the treatment of secondary carnitine deficiency in valproic acid toxicity

Trade Name (if present):
Carnitor

Date Designated 11/15/1989
Date Approved

Sponsor Contact Information
Sigma-Tau Pharmaceuticals, Inc
800 South Frederick Avenue
Gaithersburg MD 20877

Generic Name:
Levcarnitine

Designated Indication:
Treatment of manifestations of carnitine deficiency in patients with end stage renal disease who require dialysis.

Trade Name (if present):
Carnitor

Date Designated 9/6/1988
Date Approved 12/15/1999

Sponsor Contact Information
Sigma-Tau Pharmaceuticals, Inc
800 South Frederick Avenue, Suite 300
Gaithersburg MD 20877

Generic Name:
Levcarnitine

Designated Indication:
Treatment of genetic carnitine deficiency

Trade Name (if present):
Carnitor

Date Designated 2/28/1984
Date Approved 4/10/1986

Sponsor Contact Information
Sigma-Tau Pharmaceuticals, Inc
800 South Frederick Avenue
Gaithersburg MD 20877

Generic Name:
Levcarnitine

Designated Indication:
Treatment of primary and secondary carnitine deficiency of genetic origin.

Trade Name (if present):
Carnitor

Date Designated 7/26/1984
Date Approved 12/16/1992

Sponsor Contact Information
Sigma-Tau Pharmaceuticals, Inc.
800 South Frederick Avenue
Gaithersburg MD 20877

Generic Name:
(4S)-4-ethyl-4-hydroxy-3,14-dioxo-3,4,12,14-tetrahydro-1H-pyrano[3?,4?:6,7]-indolizino-[1,2-b]-quinoline-11-carbaldehyde O-(tert-butyl)-(E)-oxime

Trade Name (if present):
Gimatecan

Date Designated 11/29/2002
Date Approved

Designated Indication:
Treatment malignant glioma

Generic Name:
Centruroides immune F(ab)2

Trade Name (if present):
Alacramyn

Date Designated 6/12/2000
Date Approved

Sponsor Contact Information
Sigma-Tau Research, Inc
800 South Frederick Avenue
Suite 103
Gaithersburg MD 20877-4150

Designated Indication:
Treatment of scorpion envenomations requiring medical attention

Trade Name (if present):
Alacramyn

Sponsor Contact Information
Silanes Laboratories S A de C V.
Amores #1034 Col Del Valle
C P 03100 Mexico D F

MEXICO

Generic Name:
SB-408075

Designated Indication:
For pancreatic cancer

Trade Name (if present):

Date Designated 12/7/2000
Date Approved

Sponsor Contact Information
SmithKline Beecham Pharmaceuticals
1250 S. Collegeville Road
Collegeville PA 19426-0989

Generic Name:
Albendazole

Designated Indication:
Treatment of hydatid disease (cystic echinococcosis due to E granulosus larvae or alveolar echinococcosis due to E. multilocularis larvae)

Trade Name (if present):
Albenza

Date Designated 1/17/1996
Date Approved 6/11/1996

Sponsor Contact Information
SmithKline Beecham Pharmaceuticals
One Franklin Plaza
P O Box 7929
Philadelphia PA 19101

Generic Name:
Albendazole

Designated Indication:
Treatment of neurocysticercosis due to Taenia solium as 1) chemotherapy of parenchymal, subarachnoidal and racemose (cysts in spinal fluid) neurocysticercosis in symptomatic cases and 2) prophylaxis of epilepsy and other sequelae in asymptomatic neurocysticercosis.

Trade Name (if present):
Albenza

Date Designated 1/18/1996
Date Approved 6/11/1996

Sponsor Contact Information
SmithKline Beecham Pharmaceuticals
One Franklin Plaza
P.O. Box 7929
Philadelphia PA 19101

Generic Name:
Halofantrine

Designated Indication:

Treatment of mild to moderate acute malaria caused by susceptible strains of P falciparum and P vivax

Trade Name (if present):
Halfan

Date Designated 11/4/1991
Date Approved 7/24/1992

Sponsor Contact Information
SmithKline Beecham Pharmaceuticals
One Franklin Plaza
P.O. Box 7929
Philadelphia PA 19101

Generic Name:
Liothyronine sodium injection

Designated Indication:
Treatment of myxedema coma/precoma

Trade Name (if present):
Triostat

Date Designated 7/30/1990
Date Approved 12/31/1991

Sponsor Contact Information
SmithKline Beecham Pharmaceuticals
One Franklin Plaza
P O. Box 7929
Philadelphia PA 19101

Generic Name:
Chenodiol

Designated Indication:
For patients with radiolucent stones in well opacifying gallbladders, in whom elective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age

Trade Name (if present):
Chenix

Date Designated 9/21/1984
Date Approved 7/28/1983

Sponsor Contact Information
Solvay
901 Sawyer Road
Marietta GA 30062

Generic Name:
Selegiline HCl

Designated Indication:
As an adjuvant to levodopa and carbidopa treatment of idiopathic Parkinson's disease (paralysis agitans), postencephalitic Parkinsonism, and symptomatic Parkinsonism

Trade Name (if present):
Eldepryl

Date Designated 11/7/1984
Date Approved 6/5/1989

Sponsor Contact Information
Somerset Pharmaceuticals, Inc.
777 South Harbor Island Boulevard
Tampa FL 33602

Generic Name:
Busulfan

Designated Indication:
For use as preparative therapy for malignancies treated with bone marrow transplantation.

Trade Name (if present):
Spartaject

Date Designated 4/21/1994
Date Approved

Sponsor Contact Information
Sparta Pharmaceuticals, Inc.
111 Rock Road
Horsham PA 19044-2310

Generic Name:
RII retinamide

Designated Indication:
Treatment of myelodysplastic syndromes.

Trade Name (if present):

Date Designated 5/6/1993
Date Approved

Sponsor Contact Information
Sparta Pharmaceuticals, Inc
111 Rock Road
Horsham PA 19044-2310

Generic Name:
Sodium dichloroacetate

Designated Indication:
Treatment of lactic acidosis in patients with severe malaria

Trade Name (if present):

Date Designated 11/10/1994
Date Approved

Sponsor Contact Information
Stacpoole, Peter W M.D., Ph.D.
University Of Florida
P.O. Box 100277
Gainesville FL 32610

Generic Name:
Sodium dichloroacetate

Designated Indication:
Treatment of homozygous familial hypercholesterolemia

Trade Name (if present):

Date Designated 6/11/1990
Date Approved

Sponsor Contact Information
Stacpoole, Peter W. M D., Ph D
University of Florida
P O. Box 100277
Gainesville FL 32610

Generic Name:
Sodium dichloroacetate

Designated Indication:
Treatment of congenital lactic acidosis.

Trade Name (if present):

Date Designated 6/11/1990
Date Approved

Sponsor Contact Information
Stacpoole, Peter W. M D., Ph.D.
University of Florida
P.O. Box 100277
Gainesville FL 32610

Generic Name:
Testosterone propionate ointment 2%

Designated Indication:
Treatment of vulvar dystrophies.

Trade Name (if present):

Date Designated 7/31/1991
Date Approved

Sponsor Contact Information
Star Pharmaceuticals, Inc.
1990 N.W. 44th Street
Pompano Beach FL 33064

Generic Name:
Mycobacterium avium sensitiv RS-10

Designated Indication:
For use in the diagnosis of invasive Mycobacterium avium disease in immunocompetent individuals.

Trade Name (if present):

Date Designated 10/11/1995
Date Approved

Sponsor Contact Information
Statens Serum Institut
5 Artillerivej
DK-2300 Copenhagen S

SWEDEN

Generic Name:
Hsp E7

Designated Indication:
Treatment of recurrent respiratory papillomatosis (RRP)

Trade Name (if present):

Date Designated 3/19/2001
Date Approved

Sponsor Contact Information
StressGen Biotechnologies, Inc.
409 2nd Avenue
Suite 201
Collegeville PA 19426-2655

Generic Name:
methylbicyclone

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):

Date Designated 11/14/2002
Date Approved

Sponsor Contact Information
Sucampo Pharmaceuticals, Inc.
4733 Bethesda Ave.
Suite 450
Bethesda MD 20814

Generic Name:
3-(3,5-Dimethyl-1H-2ylmethylene)-1,3-dihydro-indol-2-one

Designated Indication:
Treatment of von Hippel-Lindau disease

Trade Name (if present):

Date Designated 3/23/2000
Date Approved

Sponsor Contact Information
Sugen, Inc.
230 East Grand Ave
South San Francisco CA 94080

Generic Name:
3-(3,5-dimethyl-1H-2ylmethylene)-1,3-dihydro-indol-2-one

Designated Indication:
Treatment of Kaposi's sarcoma.

Trade Name (if present):

Date Designated 9/11/1998
Date Approved

Sponsor Contact Information
Sugen, Inc.
230 East Grand Ave.
South San Francisco CA 94080-4811

Generic Name:
SU101

Designated Indication:
Treatment of ovarian cancer

Trade Name (if present):

Date Designated 3/12/1996
Date Approved

Sponsor Contact Information
Sugen, Inc
230 East Grand Ave.
South San Francisco CA 94080-4811

Generic Name:
SU101

Designated Indication:
Treatment of malignant glioma.

Trade Name (if present):

Date Designated 5/25/1995
Date Approved

Sponsor Contact Information
Sugen, Inc.
230 East Grand Ave.
South San Francisco CA 94080-4811

Generic Name:
decitabine

Designated Indication:
Treatment of sickle cell anemia

Trade Name (if present):

Date Designated 9/9/2002
Date Approved

Sponsor Contact Information
SuperGen, Inc
4140 Dublin Blvd , Suite 200
Dublin CA 94568

Generic Name:
busulfan

Designated Indication:
Preparative therapy for pediatric patients undergoing bone marrow transplantation

Trade Name (if present):
Partaject

Date Designated 11/25/2002
Date Approved

Sponsor Contact Information
SuperGen, Inc.
4140 Dublin Blvd
Suite 200
Dublin CA 94568

Generic Name:
rubitecan

Designated Indication:
Treatment of pediatric patients infected with human immunodeficiency virus and acquired immunodeficiency syndrome

Trade Name (if present):

Date Designated 7/17/2002
Date Approved

Sponsor Contact Information
SuperGen, Inc.
4140 Dublin Blvd
Suite 200
Dublin CA 94568

Generic Name:
Busulfan

Designated Indication:
Intrathecal therapy for neoplastic meningitis

Trade Name (if present):
Spartajet-Busulfan

Date Designated 3/5/2001
Date Approved

Sponsor Contact Information
SuperGen, Inc
4140 Dublin Boulevard
Dublin CA 94568

Generic Name:
Pentostatin

Designated Indication:
Treatment of peripheral T-cell lymphomas

Trade Name (if present):
Nipent

Date Designated 11/24/1999
Date Approved

Sponsor Contact Information
SuperGen, Inc
4140 Dublin Blvd
Suite 200
Dublin CA 94568

Generic Name:
Decitabine

Designated Indication:
Treatment of chronic myelogenous leukemia

Trade Name (if present):

Date Designated 3/8/1999
Date Approved

Sponsor Contact Information
SuperGen, Inc.
4140 Dublin Blvd.
Suite 200
Dublin CA 94568

Generic Name:
Decitabine

Designated Indication:
Treatment of myelodysplastic syndromes.

Trade Name (if present):

Date Designated 3/8/1999
Date Approved

Sponsor Contact Information
SuperGen, Inc.
4140 Dublin Blvd.
Suite 200
Dublin CA 94568

Generic Name:
Pentostatin

Designated Indication:
Treatment of cutaneous T-cell lymphoma.

Trade Name (if present):
Nipent

Date Designated 3/27/1998
Date Approved

Sponsor Contact Information
SuperGen, Inc.
4140 Dublin Blvd.
Suite 200
Dublin CA 94568

Generic Name:
Busulfan

Designated Indication:
Treatment of primary brain malignancies

Trade Name (if present):
Spartaeject

Date Designated 7/7/1997
Date Approved

Sponsor Contact Information
SuperGen, Inc
Two Annabel Lane, Suite 220
San Ramon CA 94583

Generic Name:
9-nitro-20-(S)-camptothecin

Designated Indication:
Treatment of pancreatic cancer.

Trade Name (if present):

Date Designated 9/16/1996
Date Approved

Sponsor Contact Information
SuperGen, Inc.
4140 Dublin Blvd.
Suite 200
Dublin CA 94568

Generic Name:
Etiocholanedione

Designated Indication:
Treatment of Prader-Willi syndrome.

Trade Name (if present):

Date Designated 5/7/1996
Date Approved

Sponsor Contact Information
SuperGen, Inc
Two Annabel Lane, Suite 220
San Ramon CA 94583

Generic Name:
Etiocholanedione

Designated Indication:
Treatment of aplastic anemia

Trade Name (if present):

Date Designated 11/3/1995
Date Approved

Sponsor Contact Information
SuperGen, Inc
Two Annabel Lane, Suite 220
Suite 10
San Ramon CA 94583

Generic Name:
Pentostatin

Designated Indication:
Treatment of patients with chronic lymphocytic leukemia.

Trade Name (if present):
Nipent

Date Designated 1/29/1991
Date Approved

Sponsor Contact Information
SuperGen, Inc.
4140 Dublin Blvd.
Suite 200
Dublin CA 94568
